From: Klommhaus, Kevin [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=CD18A1B1527044B0BB0248E889E73E11-KEVIN.KLOMM]
Sent: 12/30/2019 10:26:45 AM
To: Cash, Elizabeth [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e79e7b9b159746428e1d766fc34e447f-Elizabeth.C]; Svonkin, Michele [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=fc51d3541cb246c08fff060681ecc050-Michele.Svo]
CC: Lambkin, Sonya [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7d0c915e0dbb4948914f8552e911f30f-Sonya.Lambk]; Bair, Tonia [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=61b62fe2fb414fb2861003902258af2f-TBair]; Nelson, Eric [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f90377266c0c4a68bf8ac2b4783f8ac9-ENelson]; Steinberg, Nadine [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cc7979a0766747eaa65ea70be87fa51e-NSteinbe]; McCoig, Amber [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=daa97064a98f4c249e0a1264311d1169-Amber.McCoi]
Subject: CVM Concurrence memo status
Attachments: 8-01-19 CVM Concurrence Memorandum Arrow Reliance dba Darwin clean copy.docx

Good Morning Elizabeth,
I hope your holidays have been good thus far.

I wanted to reach out to you on a couple items to clarify the status. I have been working with Nadine Steinberg, to make sure we have everything lined up.

(b) (5)
[redacted]*? The attached version is the latest version I have and that version is in SharePoint.* [redacted] (b) (5)

Thank you

Sincerely

Kevin E. Klommhaus
Consumer Safety Officer
Post Market Compliance Animal Food Team
Division of Compliance
FDA/Center for Veterinary Medicine
Des Moines, IA 50309
515-244-0480 X1010
515-318-8075 cell

U.S. FOOD & DRUG

(b) (5), (b) (4)

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(b) (5), (b) (4)

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From: Erickson, Jennifer [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=824E4C5933614C1ABBAECFB412746F84-JENNIFER.ER]
Sent: 12/3/2019 10:20:56 AM
To: Lambkin, Sonya [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7d0c915e0dbb4948914f8552e911f30f-Sonya.Lambk]; Nelson, Eric [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f90377266c0c4a68bf8ac2b4783f8ac9-ENelson]
CC: Epstein, Laura [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c159926a99ce4eb1928e2027e08ade23-Laura.Epste]; Murphy, Jeanette [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=33924473c58f48519da2ce0c7f8ba851-JMURPHY]
Subject: RE: talking points for tim
Attachments: FDLI Enforcement Dr. Schell DRAFT TPs.docx

Flag: Follow up

Indeed. See attached. Jenny has reviewed and I made edits based on her comments. Laura is compiling everything she tasked the reg counsels with compiling. Admittedly these are probably too long for the amount of time he has, but I wanted to go a little more in depth so he can choose what to cover as he compiles his final talking points and have more background information if he gets questions. I think they cover what you asked Sonya to cover so we should be good.

(b) (5)

we should put numbers in let me know and I can pull them.
Jen

From: Lambkin, Sonya <Sonya.Lambkin@fda.hhs.gov>
Sent: Tuesday, December 03, 2019 9:50 AM
To: Nelson, Eric <Eric.Nelson@fda.hhs.gov>; Erickson, Jennifer <Jennifer.Erickson@fda.hhs.gov>
Subject: RE: talking points for tim

Jen confirmed that she is working on this.

From: Nelson, Eric <Eric.Nelson@fda.hhs.gov>
Date: December 3, 2019 at 9:36:33 AM EST
To: Lambkin, Sonya <Sonya.Lambkin@fda.hhs.gov>
Subject: RE: talking points for tim

Something as simple as:

(b) (5)

Eric M Nelson
Director of Compliance

FDA/Center for Veterinary Medicine (HFV-230)
7519 Standish Place
Rockville, MD 20855-2773
office: (240) 402-5642
fax: (240) 276-9241
e-mail: Eric.Nelson@fda.hhs.gov

From: Lambkin, Sonya <Sonya.Lambkin@fda.hhs.gov>
Sent: Tuesday, December 03, 2019 9:02 AM
To: Nelson, Eric <Eric.Nelson@fda.hhs.gov>
Subject: Re: talking points for tim

Good morning,
I believe that Jen may already be working on this as there was another email chain going - let me double check with her.
Thanks

From: Nelson, Eric <Eric.Nelson@fda.hhs.gov>
Date: December 3, 2019 at 8:55:36 AM EST
To: Lambkin, Sonya <Sonya.Lambkin@fda.hhs.gov>
Subject: talking points for tim

Sonya, can you put together some simple talking points for Tim to present at FDLI regarding (b) (5), what we learned and what we are doing this year. If I could get this by 2 that would be great. Sorry for the short turn around.

Eric M Nelson
Director of Compliance
FDA/Center for Veterinary Medicine (HFV-230)
7519 Standish Place
Rockville, MD 20855-2773
office: (240) 402-5642
fax: (240) 276-9241
e-mail: Eric.Nelson@fda.hhs.gov

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[redacted]

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From: Schell, Timothy [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=C9A986A0FB324D12BCBE5DC0F4153330-TIMOTHY.SCH]
Sent: 12/9/2019 8:32:02 AM
To: Nelson, Eric [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f90377266c0c4a68bf8ac2b4783f8ac9-ENelson]
Subject: FW: Talking Points for FDLI
Attachments: FDLI Enforcement Cnf 12-19 TPs for Tim.docx; (b) (5) for FDLI Enforcement.docx

Eric,

This should provide enough for your talk this week.

Tim

From: Epstein, Laura <Laura.Epstein@fda.hhs.gov>
Sent: Friday, December 6, 2019 3:33 PM
To: Schell, Timothy <Timothy.Schell@fda.hhs.gov>
Subject: Talking Points for FDLI

Tim,
I'm attaching consolidated talking points and potential questions you may get w/ answers. This was a product of joint effort from Randy, Jen, and Janice. It is quite long, partly because I separated out the three subjects on different pages and also because there are many (b) (5) QAs included. If you would like me to cut it back further, let me know. I am also attaching a longer FSMA document that Jen prepared in case you need more background. I hope the talk goes well!

Laura

Laura Epstein
Sr. Policy Advisor
Office of the Director
Center for Veterinary Medicine, FDA
301-796-8558

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From: Douglas Lueders [aafco.doug@gmail.com]
Sent: 12/10/2019 5:11:43 PM
To: Bowers, Ken [KDA] [ken.bowers@ks.gov]; Burkholder, William [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8d5fda60a4814bd290d84bd28a2a9292-BBURKHOL]; Campbell, Janet [jrcampbell@landolakes.com]; mike.davidson@cdfa.ca.gov; meghan.dicks@adm.com; Dzanis@aol.com; bob@nasda.org; dfairfield@ngfa.org; StateRFR-Ferguson, George [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4dd46592837047d8bb41b6ff84b7f9b7-George.Ferg]; jfidenzio@americanpetproducts.org; StateRFR-Geiger, Robert [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=064d353aa9654516aeb6ced2a1a92ad2-RobertGeige]; Green, Kristen M. [kristen.mary.green@uky.edu]; Emily Bulian Helmes [ebhelmes@elanco.com]; darrell.johnson@uky.edu; StateRFR-Jones, Ben [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=79f4742dab424260a61614186aa1abd9-BenJones]; Douglas Lueders [AAFCO.DOUG@gmail.com]; Nelson, Eric [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f90377266c0c4a68bf8ac2b4783f8ac9-ENelson]; StateRFR-Teneyck, Richard [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ed6fce9a806d4043bb1b53f98b2f1915-RichardTene]; Angele Thompson [tpettec@gmail.com]; Pat@petfoodinstitute.org; syounker@milkspecialties.com; Ziehr - CDA, Scott [scott.ziehr@state.co.us]; StateRFR-Therrell, Austin [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2a33cb63b8ec49ad984af69c85ffc3c3-Austin.Ther]; Jennifer Roland [JenniferR@assochq.org]; Jason Schmidt [jasonschmidt@ldaf.state.la.us]; Lizette (AGR) Beckman [lbeckman@agr.wa.gov]; Pillai, Padmakumar [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=22deaf5039ee4e9e8ef4db3524161ef5-PPILLAI]
Subject: Re: DRAFT Albuquerque MBRC agenda
Attachments: 2020 Albuquerque MBRC agenda FINAL.docx; 20190403_SUIP27WorkgroupReport[kv1711213-1711214][kv1739820-1739821] (1).docx; Proposed Revision to PF3 - 100719[kv1739806-1739807][kv1740820-1740821] (1).docx; Proposed Revision to PF5 - 100719[kv1739814-1739815][kv1740824-1740825] (1) (1).docx; Proposed Revision to PF7 & Feeding Protocols Corrected 8-29-2019[kv1739830-1739831] (1) (1).docx

Good afternoon all,
Please see the significantly modified "final" MBRC agenda for Albuquerque. The PFC recently sent some requests for MBRC action. Jason and I just worked out the attachments for the PFC initiatives. Please take some time to review all the attachments (A-F) so that we can have informed discussion during the meeting. There is a lot on our table so your pre-meeting review will help us fit everything into our allotted time. Please holler if you have any questions or concerns.
I hope to see you all in Albuquerque. I wish you all a merry Christmas, joyous New Year and safe travels wherever you are headed.

Regards,
Doug Lueders
AAFCO MBRC Chair
651-448-1100

On Mon, Nov 11, 2019 at 3:14 PM Douglas Lueders <aafco.doug@gmail.com> wrote:

> Good afternoon all.
> Please see the attached Draft Agenda for the MBRC Meeting in Albuquerque. It is a a relatively light agenda. As always I'm open for additional suggestions. Please review your daily feed (animal food) work and see if there are issues that could use MBRC input and let me know.
>
> Regards,
> Doug Lueders
> AAFCO MBRC Chair

651-448-1100

Model Bills and Regulations Committee Agenda

AAFCO 1800 South Oak Street, Suite 100 Champaign, IL

AAFCO 2020 Midyear Meeting
Hyatt-Regency
Grand Pavilion Ballroom 1-5, 2nd Floor
Albuquerque, NM
1:00 pm – 2:00 pm January 21, 2020

Agenda Topics:

1. Welcome and Committee Member Introductions

2. Louisville Minutes (approved as written on 10/1), posted on AAFCO web-site and in the Feed BIN, included in the General Session packet)

3. October 25-30 E-meeting report on Expression of Guarantees working group recommendation (Approved as proposed on 10/30), posted on AAFCO web-site and in the Feed BIN, included in the General Session packet)

4. Working Group reports and recommendations
    a.) Regulation 4 Expression of Guarantees – thanks and disband
    b.) SUIP 27 Chews and Bones (Attachment C) – Jason/Liz

5. Old Business
    a.) Addition of Regulation 6(h) (Attachment A) Ali/Richard
    b.) Revision to Section 7.[xe "Adulteration"] Adulteration (Attachment B) Doug

6. New Business
    a.) Proposed revision for Regulation PF3 Brand and Product Names (Attachment D) Jason/Liz
    b.) Proposed revision for Regulation PF5 Ingredients (Attachment E) Jason/Liz
    c.) Proposed revision for Regulation PF7 Nutritional Adequacy (Attachment F) Jason/Liz
    d.) Chapter 4 Definitions of Words and Terms vs. Chapter 6 Feed Terms and Definitions, Bob G.
    e.) Model language vs. adoption by rule discussion

7. Assignments/homework for annual meeting

8. Adjourn

Attachment A – Proposed Addition of Regulation 6(h)

Recommends adding Regulation 6(h) language regarding **Carriers** (as below) to Regulation 6 of the Model Bill. Move SUIP 17 – Carriers – to the deleted SUIP list if/when 6(h) is approved by the AAFCO membership.

> *6(h) Each carrier shall be listed in the ingredient statement on the label unless it meets the criteria for an incidental ingredient [21 CFR 501.100(a)(3)].*

Attachment B – Proposed Revision to Section 7.[xe "Adulteration"] Adulteration

A commercial feed shall be deemed to be adulterated:

(a)

(1) If it bears or contains any poisonous or deleterious substance which may render it injurious to human or animal health; but in case the substance is not an added substance, such commercial feed shall not be considered adulterated under this subsection if the quantity of such substance in such commercial feed does not ordinarily render it injurious to human or animal health; or

SUIP 27 Chews and Bones (ATTACHMENT C)

Pet Food Committee Recommendation:
The PFC agrees with both of the recommendations made by the workgroup and advocates that the MBRC do likewise.

Background
The SUIP 27 Workgroup was charged with considering the possible inclusion of SUIP 27 into Model Bill Pet Food Regulations as PF12(d).

Discussion
After discussion and gathering information from states (see survey results below), the workgroup recommends the policy regarding chews, bones and toys to remain in the Statements for Uniformity Interpretation and Policy section due to the nature of its flexibility to be adopted as policy.

Additionally, we recommend the data captured in the survey also be retained in the record (see attachment) and stay with SUIP 27 due to the variety of ways this SUIP is used. It is also recommended per comments from the survey that SUIP 27 be updated to address (where possible) issues and concerns. We recommend that the PFC send this back to Model Bills and Regulations Committee for that consideration.

Workgroup Recommendations:

1. The Workgroup recommends the policy regarding chews, bones and toys to remain in the Statements for Uniformity Interpretation and Policy (SUIP) section due to the nature of its flexibility to be adopted as policy, and; due to the variety of ways this SUIP is reported to be used, that the data captured in the survey also be retained in the record and stay with SUIP 27; and recommends the MBRC consider likewise.

2. Based upon comments captured as part of the survey conducted by the SUIP 27 Workgroup, the workgroup recommends that SUIP 27 be reviewed to address issues and concerns and, subsequently, updated where possible to address such; and asks that the MBRC consider likewise.

Please select your state:	**1. Does your state adopt by reference to the Official Publication (OP) (e.g., when changes are made to model regulation does this automatically take effect in your state)?**	**2. Does your state require product registration of chews, bones and toys for pet and specialty pets?**	**3. Does your state allow the exemptions from registration per SUIP 27 (chews, bones and toys for pet and specialty pets)?**	**4. Does your state require label submission of such products?**	**5. Which do you reference?**	**6. If your state has its own policy how does it differ from the SUIP?**	**7. Are there issues applying the policy, if so please explain?**
North Carolina	No	No	Yes	No	SUIP 27		Our only issue is that our law does not allow for an exemption from registration, only an exemption from the definition of a "Commercial Feed". With that said, we still do the exemption and have received no complaints, but our legal counsel has advised us that we are not in compliance with our own law.
Idaho	No	No	Yes	Yes	State Policy	The SUIP was codified as a stand alone rule so any language changes to the SUIP would put it at odds with Idaho law. Whether it is kept as a SUIP or added to the model bill would make no difference.	
Pennsylvania	No	No	Yes	No	State Policy	Our policy agrees with SUIP27, except we would require man-made items (i.e. No-Hide Chews or other products manufactured from combining food ingredients) to contain a guaranteed analysis and the firm be licensed. Only products made from natural parts of an animal we would exempt. We also exempt plastic/rubber chew toys. This policy is not written anywhere, it's just something that we do.	
Pennsylvania	No	No	Yes	No	SUIP 27		No issues

Please select your state:	1. Does your state adopt by reference to the Official Publication (OP) (e.g., when changes are made to model regulation does this automatically take effect in your state)?	2. Does your state require product registration of chews, bones and toys for pet and specialty pets?	3. Does your state allow the exemptions from registration per SUIP 27 (chews, bones and toys for pet and specialty pets)?	4. Does your state require label submission of such products?	5. Which do you reference?	6. If your state has its own policy how does it differ from the SUIP?	7. Are there issues applying the policy, if so please explain?
Massachusetts	Yes	No	Yes	Yes	Neither	Registration of chews, bones or toys depends. If said products have a ga or a flavor, or provide any nutrition, I would require registration and labels. If it is strictly a chew or toy that the pet just gnaws on, then it would be exempt.	
Wisconsin	No	No	Yes	No	Neither	Technically the exemption is in our state law. Exact language from rule, Wisconsin Administrative Code ATCP 42.28(2)(b): Exemption. Subsection (1) [labeling] does not apply to any of the following:...Pet chews, bones, toys, or exercisers made of rawhide, wood, or man-made material, whether flavored or unflavored, unless the manufacturer or distributor claims that the product is intended for use as a dog or cat food or that it provides anything of nutritional value to a dog or cat. Essentially, chews, bones, etc. are explicitly exempt from LABELING, but not licensing and tonnage (if you read the law literally). That said, if a firm is solely in the business of chews, they are not required to be licensed because chews are not intended for nutritive purpose, therefore those items are not considered commercial feed. If adulterated, Wisconsin would have jurisdiction to investigate, as adulteration law is broader.	n/a
Iowa	Yes	Yes	Yes	Yes	Both		

Please select your state:	1. Does your state adopt by reference to the Official Publication (OP) (e.g., when changes are made to model regulation does this automatically take effect in your state)?	2. Does your state require product registration of chews, bones and toys for pet and specialty pets?	3. Does your state allow the exemptions from registration per SUIP 27 (chews, bones and toys for pet and specialty pets)?	4. Does your state require label submission of such products?	5. Which do you reference?	6. If your state has its own policy how does it differ from the SUIP?	7. Are there issues applying the policy, if so please explain?
North Dakota	No	No	Yes	No	Both		The only issue we have encountered is companies trying to expand the exemption to include multi ingredient products or products not referenced in SUIP #27.
Virginia	No	No	Yes	Yes	Both	Our Law states, "The Commissioner may adopt as a regulation." thus we do not automatically change our policies if this is included in the model bill. However, we almost always follow AAFCO standards.	Currently, we follow SUIP 27, so it would not be a problem. As long as there are no nutritional claims we exempt the product from registration.
New York	No	No	Yes	Yes	SUIP 27		
South Carolina	No	No	Yes	No	SUIP 27		
New Hampshire	No	No	Yes	No	SUIP 27		At times, there are some products that fall in a gray area. Some companies feel that any "single ingredient" product is exempt for feed regulations. There are some "single ingredient" products that been processed and will be consumed by the dog, therefore could fall under the definition of feed. One example, fish skins that are smoked and 100% edible. Thanks!
Missouri	No	Yes	Yes	No	State Policy	Missouri uses the SUIP exactly as written as our policy (not written into our Law) for Chews Bones and Toys.	We have no provisions in our Law for adoption of anything from AAFCO other than feed terms and ingredient definitions. Our Law automatically adopts CFR unless the director proclaims otherwise.

Please select your state:	1. Does your state adopt by reference to the Official Publication (OP) (e.g., when changes are made to model regulation does this automatically take effect in your state)?	2. Does your state require product registration of chews, bones and toys for pet and specialty pets?	3. Does your state allow the exemptions from registration per SUIP 27 (chews, bones and toys for pet and specialty pets)?	4. Does your state require label submission of such products?	5. Which do you reference?	6. If your state has its own policy how does it differ from the SUIP?	7. Are there issues applying the policy, if so please explain?
Texas	No	No	Yes	No	SUIP 27		
Washington	Yes	Yes	Yes	Yes	State Policy	N/A	The main issues that come up is the companies being unaware that if there is any indication of nutritional intention on the products labeling or website information, that it is no longer exempt. They communicate that they were unaware that "highly digestible" or "Great source of protein" takes away it's exemption, along with items like a Guaranteed Analysis and Calorie Content Statements.
Utah	Yes	No	Yes	No	SUIP 27		
Kansas	Yes	No	Yes	No	SUIP 27		
Kentucky	No	No	Yes	No	State Policy		
Minnesota	No	No	Yes	No	State Policy		There are issues identifying when a product meets the exemption or not. MN has chosen to treat the list identified in the SUIP as an exclusive list, but products frequently come up that that could easily be considered a chew (trachea, feet, tails, etc.) but aren't called out by name in the exemption. It would be helpful to have the language expanded to include more or say it is not limited to those particular products. If the intention IS to limit it to those products, that should be stated explicitly.

Please select your state:	1. Does your state adopt by reference to the Official Publication (OP) (e.g., when changes are made to model regulation does this automatically take effect in your state)?	2. Does your state require product registration of chews, bones and toys for pet and specialty pets?	3. Does your state allow the exemptions from registration per SUIP 27 (chews, bones and toys for pet and specialty pets)?	4. Does your state require label submission of such products?	5. Which do you reference?	6. If your state has its own policy how does it differ from the SUIP?	7. Are there issues applying the policy, if so please explain?
Colorado	No	Yes	No	Yes	State Policy	Colorado registers chews. Chews do not need to have a GA. CO does not register bones or toys.	
Louisiana	No	Yes	No	Yes	Neither	According to Louisiana statute, "Commercial feed means all materials...which are distributed for use as pet food or as feed for livestock..." The British dictionary defines food as "any substance containing nutrients [i.e. protein, fat, fiber] that can be ingested by a living organism and metabolized into energy and body tissue". Therefore, this department registers all materials that contain protein, fat, fiber, minerals, etc. regardless of its intended use as a recreational aid. However, this department exercises regulatory discretion when it comes to the GA label requirements on these items.	

AAFCO
Association of American Feed Control Officials

Proposed Revision to PF3 (ATTACHMENT D)

Pet Food Committee Recommendation:
The PFC recommends that the following revisions be considered by the MBRC for integration into the AAFCO Official Publication.

Background
Methods used to calculate the ingredient inclusion rates for percentage claims on pet food labels has become inconsistent and possibly misleading to the consumer. This workgroup was formed to review current regulations and provide recommendations to the committee.

Workgroup Recommendations:

Regulation PF3. Brand and Product Names

(a) The names of the ingredient(s) used in the brand or product name or elsewhere on the product label shall appear in order of predominance by weight in the product. Names of flavors due to their varying intensity can be in any order.

(b) The words "100%," or "All," or words of similar designation shall not be used in the brand or product name of a pet food or specialty pet food if the product contains more than one ingredient. ~~, not including water sufficient for processing, decharacterizing agents, or trace amounts of preservatives and condiments.~~

(c) An ingredient or combination of ingredients may form part of a brand or product name of a pet food or specialty pet food:

  (1) When the named ingredient(s) constitutes at least 95% of the total weight of the product. Water sufficient for processing may be excluded when calculating the percentage; however, the named ingredients shall constitute at least 70% of the total product weight.

  (2) When any named ingredient(s) constitutes at least 25% of the total weight of the product, provided that:

    A. Water sufficient for processing may be excluded when calculating the percentage, however, the named ingredients(s) shall constitute at least 10% of the total product weight; and

    B. A descriptor is used with the ingredient name(s). This descriptor shall imply other ingredients are included in the product formula.

    Examples of descriptors include "dinner," "platter," "entree," "formula," and "recipe"; and

    C. The descriptor shall be in the same size, style and color print as the ingredient names(s)

  (3) When a combination of ingredients which are included in the brand or product name in accordance with Regulation PF3(c) provided that: ~~meets all of the following:~~

A. Each named ingredient constitutes at least 3% of the total weight of the product ~~the product weight~~, excluding water sufficient for processing; and

~~B. The names of the ingredients appear in the order of their respective predominance by weight in the product; and~~

B. All such ingredient names appear on the label in the same print size, font style and color print.

(d) When the name of any ingredient appears in the brand or product name of a pet food or specialty pet food or elsewhere on the product label and includes a descriptor such as "with" or similar designation, the named ingredient(s) must each constitute at least 3% of the product weight exclusive of water sufficient for processing. ~~If the names of more than one ingredient are shown, they shall appear in their respective order of predominance by weight in the product.~~

The 3% minimum level shall not apply to claims for nutrients, such as, but not limited to, vitamins, minerals, and fatty acids, as well as condiments. The word "with," or similar designation, and named ingredients shall be in the same size, style, color and case print and be of no greater size than:

Panel Size	Max "With Claim" Type Size
≤5 in.^{2}	1/8 in.
>5–≤25 in.^{2}	1/4 in.
>25–≤100 in.^{2}	3/8 in.
>100–≤400 in.^{2}	1/2 in.
>400 in.^{2}	1 in.

(e) A flavor designation may be included as part of the product name or elsewhere on the label of a pet food or specialty pet food when the flavor designation meets all of the following:

(1) The flavor designation:

A. Conforms to the name of the ingredient as listed in the ingredient statement; or

B. Is identified by the source of the flavor in the ingredient statement; and

(2) The word "flavor" is printed in the same size type and with an equal degree of conspicuousness as the name of the flavor designation; and

(3) Substantiation of the flavor designation, the flavor claim, or the ingredient source is provided upon request.

(f) Contractions or coined names referring to ingredients shall not be used in the brand name of a pet food or specialty pet food unless it is in compliance with Regulation PF3 (b), (c), or (d).

(g) When pet food or specialty pet food consists of raw milk, the words, "Raw (blank) Milk" shall appear conspicuously on the principal display panel. (Blank is to be completed by using the species of animal from which the raw milk is collected.)

AAFCO
Association of American Feed Control Officials

Proposed Revision to PF5 (ATTACHMENT E)

Pet Food Committee Recommendation:

The PFC recommends that the following revisions be considered by the MBRC for integration into the AAFCO Official Publication.

Background

Methods used to calculate the ingredient inclusion rates for percentage claims on pet food labels has become inconsistent and possibly misleading to the consumer. This workgroup was formed to review current regulations and provide recommendations to the committee.

Workgroup Recommendations:

Regulation PF5. Ingredients

(a) Each ingredient of a pet food or specialty pet food shall be listed in the ingredient statement as follows:

  (1) The names of all ingredients in the ingredient statement shall be shown in letters or type of the same size, style and color;

  (2) The ingredients shall be listed in descending order by their predominance by weight in non-quantitative terms;

  (3) Ingredients shall be listed and identified by the name and definition established by AAFCO; and

  (4) Any ingredient for which no name and definition have been so established shall be identified by the common or usual name of the ingredient.

(b) The ingredients "meat" or "meat by-products" shall be qualified to designate the animal from which the meat or meat by-products are derived unless the meat or meat by-products are derived from cattle, swine, sheep, goats, or any combination thereof. For example, ingredients derived from horses shall be listed as "horsemeat" or "horsemeat by-products."

(c) Brand or trade names shall not be used in the ingredient statement.

(d) A reference to the quality, nature, form, or other attribute of an ingredient shall be allowed when the reference meets all of the following:

  (1) The designation is not false or misleading;

  (2) The ingredient imparts a distinctive characteristic to the pet food or specialty pet food because it possesses that attribute; and

  (3) A reference to quality or grade of the ingredient does not appear in the ingredient statement.

(e) Any reference to the percentage of an ingredient or combination of ingredients, by symbol or word, in the brand or product name or elsewhere on a pet food or specialty food label, shall be based in relation to the total weight of all ingredients in the product.

  (1) The names of the ingredient(s) shall appear in order of predominance by weight in the product, provided that names of flavors due to their varying intensity can be in any order.

  (2) Where water sufficient for processing is excluded from the declared percentage, the exclusion of water shall be indicated in words juxtaposed to, the same style and color print and at least one-half the print size of the stated percentage (e.g., "95% beef exclusive of water" or "95 percent chicken and liver exclusive of water").

AAFCO
Association of American Feed Control Officials

Proposed Revision to PF7 & Feeding Protocols (ATTACHMENT F)

Pet Food Committee Recommendation:

The PFC recommends that the following revisions be considered by the MBRC for integration into the AAFCO Official Publication.

Background

Revising requirements to the Feeding Protocols to account for the special nutritional requirements for growth of large size dogs. DRAFT language.

> **Note:**
> _Revised for correct formatting, clarity and plain language, and to include wording to be placed in the Protocols Section of the OP.

Workgroup Recommendations:

Regulation PF7. Nutritional Adequacy

(a) The label of a pet food or specialty pet food which is intended for all life stages and sizes of the pet or specialty pet may include an unqualified claim, directly or indirectly, such as "complete and balanced," "perfect," "scientific," or "100% nutritious" if at least one of the following apply:
  (1) The product meets the nutrient requirements for all life stages and sizes established by an AAFCO-recognized nutrient profile; or
  (2) The product meets the criteria for all life stages as substantiated by completion of the appropriate AAFCO-recognized animal feeding protocol(s);
    A. Unqualified claims of nutritional adequacy that include large size dogs can be substantiated by completing the appropriate protocols using large size dogs; or
    B. Can be substantiated by completing the appropriate protocols using dogs less than 70 lbs. adult weight while containing no more calcium and phosphorus than the maximum limits for large size dogs listed in the AAFCO Dog Food Nutrient

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Profiles; or

(3) The product is a member of a product family which is nutritionally similar to a lead product which contains a combination of ingredients that has been fed to a normal animal as the sole source of nourishment in accordance with the testing procedures established by AAFCO for all life stages, provided that:

A. The nutritional similarity of the family product can be substantiated according to the Procedures for Establishing Pet Food Product Families developed by AAFCO; and

B. The family product meets the criteria for all life stages; and

C. Under circumstances of reasonable doubt, the (State Control Official) may require the manufacturer to perform additional testing of the family product in order to substantiate the claim of nutritional adequacy.

(b) The label of a pet food or specialty pet food which is intended for a limited purpose (such as size of dog) or a specific life stage, but not for all life stages and sizes, may include a qualified claim such as "complete and balanced," "perfect," "scientific," or "100% nutritious" when the product and claim meet all of the following:

(1) The claim is qualified with a statement of the limited purpose or specific life stage for which the product is intended or suitable, for example, "complete and balanced for puppies (or kittens)." The claim and the required qualification shall be juxtaposed on the same label panel and in the same size, style and color print; and

(2) The product meets at least one of the following:

~~A.~~ The nutrient requirements for the limited purpose or specific life stage established by an AAFCO-recognized nutrient profile; or

A.

B. The criteria for a limited purpose or a specific life stage as substantiated by completion of the appropriate AAFCO-recognized animal feeding protocol(s);

i.

~~A.~~ Qualified claims of nutritional adequacy that include large size dogs can be substantiated by ~~:~~ completing the appropriate protocols ~~with~~ using large size dogs; or

~~(3)~~ ii.

~~B.~~ Can be substantiated by ~~completion~~ completing the ~~of~~ appropriate protocols ~~with~~ using dogs less than 70 lbs. adult weight while containing no more ~~complying with the~~ calcium and phosphorus than the maximum limits for large size dogs listed in the AAFCO Dog Food Nutrient Profiles; or

~~A.~~ ~~or~~

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~~B.~~C. The requirements of a product family which is nutritionally similar to a lead product which contains a combination of ingredients which, when fed for such limited purpose, will satisfy the nutrient requirements for such limited purpose and has had its capabilities in this regard demonstrated by adequate testing, and provided that:

i. The nutritional similarity of the family product can be substantiated according to the Procedures for Establishing Pet Food Product Families developed by AAFCO; and
ii. The family product meets the criteria for such limited purpose; and
iii. Under circumstances of reasonable doubt, the (State Control Official) may require the manufacturer to perform additional testing for the family product to substantiate the claim of nutritional adequacy.

(c) Dog and cat food labels shall include a statement of nutritional adequacy or purpose of the product except when the dog or cat food is clearly and …

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Language for Insertion into the Feeding Protocols (in red)

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AAFCO Dog and Cat Food Nutrient Profiles—Introduction

The Pet Food committee recommends that the revisions to the AAFCO Dog and Cat Food Nutrient Profiles not be enforced until 12 months (1/1/2017) for new products in development and 24 months (1/1/2018) for existing products after publication of the revised AAFCO Dog and Cat Food Nutrient Profiles in the print version of the AAFCO OP.

[…]

The established profiles are the "AAFCO Dog Food Nutrient Profiles" and "AAFCO Cat Food Nutrient Profiles" as the terms are applied in AAFCO model pet food regulations referring to nutritional adequacy. Under these model regulations, dog and cat foods substantiated for nutritional adequacy by reference to the AAFCO Dog and Cat Food Nutrient Profiles for a designated life stage(s) must be formulated to contain at least the minimum concentrations of nutrients specified in the Profiles, and, for some nutrients, not more than any maximum concentration listed for that specific nutrient in the Profiles as shown in this section. Products with their nutritional adequacy substantiated by AAFCO Feeding Protocols are not mandated to meet the minimum or maximum concentrations listed in the Profiles, except for large-size dogs growth and all life stage products substantiated by the protocols using non-large size dogs must contain no more than the maximum large size breed calcium and phosphorus concentrations listed in the profiles. Additionally, snacks, treats or products intended for intermittent or supplemental feeding only are not mandated to meet the concentrations in the Profiles unless their labeling references the Profiles.

[…]

~~AAFCO DOG AND CAT FOOD F~~[XE "Feeding protocols"]~~EEDING PROTOCOLS~~

~~[…]~~

MINIMUM FEEDING PROTOCOL FOR PROVING AN UNQUALIFIED REPRESENTATION OF NUTRITIONAL ADEQUACY FOR A DOG OR CAT FOOD

The minimum testing necessary to prove an unqualified claim for nutritional adequacy may be obtained by using the gestation/lactation and the growth protocols.

[…]

Test puppies or kittens shall receive the test diet as their sole source of nourishment, other than dam's or queen's milk, during lactation, weaning, and growth.

Selection of puppies or kittens shall be on a statistically sound basis from each of the litters qualifying for the gestation/lactation protocol with equal sex distribution preferred.

Unqualified claims of nutritional adequacy for a product to be fed to large size dogs can be substantiated by completing the gestation/lactation and the growth protocols using large size dogs or can be substantiated by completing the gestation/lactation and the growth protocols with dogs less than 70 lbs. adult weight in which the product contains no more calcium and phosphorus than the maximum limits for large size dogs listed in the AAFCO Dog Food Nutrient Profiles.

[…]

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MINIMUM FEEDING PROTOCOL FOR PROVING A GROWTH CLAIM FOR A DOG FOOD

PUPPIES

A minimum of eight puppies from three different bitches shall be required to start the test.

[…]

The test group shall have the same gender distribution as the concurrent control group.

A growth claim of nutritional adequacy for a product that includes large size dogs can be substantiated by completing the growth protocol using large size dogs or can be substantiated by completing the growth protocol using dogs less than 70 lbs. adult weight in which the product contains no more calcium and phosphorus than the maximum limits for large size dogs listed in the AAFCO Dog Food Nutrient Profiles.

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~~(c)~~ […]

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~~**AAFCO Methods for Substantiating Nutritional Adequacy of Dog and Cat Foods**~~

~~**This section contains the minimum testing methods for the substantiation of nutritional adequacy claims, calorie content claims, and procedures for establishing pet food product families referenced in AAFCO Model Pet Food and Specialty Pet Food Regulations PF2, 4, 7, 8, 9 and/or 10. These methods represent minimum requirements. Companies may choose, or may need, to perform additional testing to substantiate their claims.**~~

~~**AAFCO Dog and Cat Food Nutrient Profiles—Introduction**~~

~~The Pet Food committee recommends that the revisions to the AAFCO Dog and Cat Food Nutrient Profiles not be enforced until 12 months (1/1/2017) for new products in development and 24 months (1/1/2018) for existing products after publication of the revised AAFCO Dog and Cat Food Nutrient Profiles in the~~

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~~print version of the AAFCO OP.~~

~~The Pet Food committee also recommends that the revisions to PF7 of the Pet Food Model Regulations for Pet and Specialty Pet Food Under the Model Bill not be enforced until enforcement commences for the revised AAFCO Dog and Cat Food Nutrient Profiles.~~

~~Delayed enforcement and implementation of the revised PF7 language for nutritional adequacy statements would allow nutritional adequacy statements on products in the market place to be either: verbatim as shown in 2014 OP hard copy, or verbatim~~

~~as shown in the OP hard copy containing the revised nutrient profiles, until 24 months after publication of the revised nutrient profiles at which time the statement must be as verbatim in the revised PF7.~~

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~~The original Canine and Feline Nutrition Expert Subcommittees convened in 1990 were charged by the chair of the AAFCO Pet Food Committee to establish practical nutrient profiles for both dog and cat foods based on commonly used ingredients. These subcommittees established the "AAFCO Dog Food Nutrient Profiles" and the "AAFCO Cat Food Nutrient Profiles" that appeared in the Official Publication of the AAFCO in 1992 and 1993, respectively. The profiles were reviewed in 1994/95 and updates to the maximum concentrations for vitamin A in dog foods were implemented in 1996. The National Research Council (NRC) in 2006 updated its published *Nutrient Requirements of Dogs* and *Nutrient Requirements of Cats* in a single publication that combined recommendations for both species.[1]In 2007 the AAFCO Pet Food Committee again formed Canine and Feline Nutrition Expert Subcommittees and charged these subcommittees with the task of revising the AAFCO Nutrient Profiles in consideration of the~~

~~information in the 2006 NRC *Nutrient Requirements of Dogs and Cats* (2006 NRC). In addition, the subcommittees considered information in the NRC *Mineral Tolerance of Animals Second Revised Edition, 2005* (2005 *Mineral Tolerance of Animals*).[2] Finally, the subcommittees also reviewed and considered the recommended nutrient concentrations for dog and cat food products as published in February 2008 by the European Pet Food Industry Federation (Federation Europeenne de l'Industrie des Alimentis pour Animaux Familiers (FEDIAF)), titled *F.E.D.I.A.F. Nutritional Guidelines for Complete and Complementary Pet Food for Cats and Dogs*, (FEDIAF Guidelines) that are roughly the European equivalent to the AAFCO Dog and Cat Food Nutrient Profiles.[3]~~

~~The AAFCO Dog and Cat Food Nutrient Profiles were designed to establish practical minimum and some maximum nutrient concentrations for dog and cat foods, formulated from commonly used, non-purified, complex ingredients. The concentrations differ from minimum nutrient requirements traditionally developed by the NRC Committee on Animal Nutrition. Many of the NRC minimum nutrient requirements are based on research with purified diets and/or highly bioavailable nutrient sources that are not practical to use in commercial dog and cat foods. Therefore, unlike the previous NRC publications *Nutrient Requirements of Dogs* in 1985[4] and *Nutrient Requirements of Cats* in 1986,[5] the *Nutrient Requirements of Dogs and Cats* in 2006 contained two additional listings of nutrient concentrations for adequate intake and recommended allowance (RA) in addition to minimum requirements. The concentrations for RA's of nutrients in the 2006 NRC are at least equal to, or greater than, concentrations for adequate intakes and minimum requirements, respectively, and are defined as "the concentration or amount of a nutrient in a diet formulated to support a given physiological state." When appropriate, the RA takes into consideration the~~

~~bioavailability of the nutrient. Thus, the Canine~~

~~and Feline Nutrition Expert Subcommittees of 2007 primarily used the RA in the 2006~~

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~~*Nutrient Requirements of Dogs and Cats* in evaluating whether revision was needed to one or more of the minimum recommended concentrations in the profiles. Values for specific nutrient concentrations were added or modified where indicated and supported by recent scientific publications, practical experience, or unpublished data.~~

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~~The AAFCO Dog and Cat Food Nutrient Profiles have been criticized and faulted for not explicitly indicating the apparent nutrient digestibility, sometimes called nutrient availability or bioavailability, required to make the listed concentrations adequate~~

~~for meeting the animal's daily requirements. When a minimum requirement has been established for a particular nutrient, the expected apparent digestibility to meet the minimum requirement for that nutrient at the recommended concentration listed in an AAFCO Nutrient Profile can be calculated using the formula:~~

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~~[(minimum requirement) × (its apparent digestibility in the diet(s) used to establish the minimum requirement)/(recommended concentration in the AAFCO Profile)] × 100.~~

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~~In the above formula, the minimum requirement is expressed in the same units as in the AAFCO Nutrient Profile and digestibility is expressed in decimal equivalents. As an example, the NRC lists the minimum crude protein requirement for puppies to be met by formulas containing 18% crude protein on a dry matter basis with the digestibility of the protein sources~~

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~~estimated to be near 100%. The 2016 AAFCO Dog Food Nutrient Profile for Growth and Reproduction recommends the minimum crude protein concentration of dry matter to be 22.5%. Therefore, the expected apparent digestibility for crude protein~~

~~in a diet formulated to meet the AAFCO Dog Food Nutrient Profile for Growth and Reproduction is at least 80% [(18 × (1.00)/22.5) × 100].~~

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~~For nutrients known to be essential, but that lack sufficient data to establish a minimum requirement, the typical digestibility for the nutrient in ingredients and food matrices similar to those used to establish the apparent amount to fulfill the animal's need for the nutrient should be ensured. The 2006~~ ~~*Nutrient Requirements of Dogs and Cats*~~ ~~discusses average or typical apparent digestibility for such nutrients when explaining how a RA was set. As an example, for adult dogs there is no established minimum requirement for iron, although iron is considered essential for adult dogs. In setting the RA of 30 mg/kg in dietary dry matter for adult maintenance, the NRC subcommittee considered the apparent digestibility of iron to be 20%. However, the explanatory text in the publication notes that measured apparent digestibility of iron in the scientific literature has ranged from close to 100% to less than 10%, and is affected by numerous factors such as the specific source of iron, the concentration of other specific minerals or other ingredients in the diet, as well as the iron status of the animal.~~

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~~The specific example for iron can be generalized to most essential minerals, and demonstrates the impossibility that any list of concentrations can invariably ensure that all nutrient requirements are fulfilled in all diet formulas without additional considerations. As stated for the previous editions of the AAFCO Dog and Cat Food Nutrient Profiles, formulating a product according to the Profiles is only~~

~~one part of a nutritionally sound, scientific development that must consider all other aspects of the~~

~~product. The fact that a dog or cat food is formulated to meet a specific AAFCO Profile should not deter or discourage the manufacturer from conducting appropriate feeding trials to further confirm and ensure the diet is nutritionally adequate for its intended use.~~

~~Indications regarding expected nutrient availability from some ingredient sources are given in footnotes. It is important to read the footnotes to the tables as they contain information critical to many of the recommended concentrations. Additionally, manufacturers must make allowances to nutrient concentrations prior to processing~~

~~to account for losses during processing and subsequent storage. The recommended concentrations in the Profiles are those expected to be present at the time the formula is consumed by the animal.~~

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~~The established profiles are the "AAFCO Dog Food Nutrient Profiles" and "AAFCO Cat Food Nutrient Profiles" as the terms are applied in AAFCO model pet food regulations referring to nutritional adequacy. Under these model regulations, dog and~~

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~~cat foods substantiated for nutritional adequacy by reference to the AAFCO Dog and Cat Food Nutrient Profiles for a designated life stage(s) must be formulated to contain at least the minimum concentrations of nutrients specified in the Profiles, and, for some~~

~~nutrients, not more than any maximum concentration listed for that specific nutrient in the Profiles as shown in this section. Products with their nutritional adequacy substantiated by AAFCO Feeding Protocols are not mandated to meet the minimum or maximum concentrations listed in the Profiles. Additionally,~~

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~~snacks, treats or products intended for intermittent or supplemental feeding only are not mandated to meet the concentrations in the Profiles unless their labeling references the Profiles.~~

~~The AAFCO Dog and Cat Food Nutrient Profiles and the AAFCO Feeding Protocols are the only methods recognized by AAFCO for substantiating the nutritional adequacy of "complete and balanced" dog or cat foods. If a product is substantiated by a feeding trial and does not meet the AAFCO Dog or Cat Food Nutrient Profiles, the label cannot reference the Profiles. An unqualified reference to an AAFCO Dog or Cat Food Nutrient Profile is an implied guarantee that the product contains the minimum concentrations~~

~~for all nutrients in the profile and no more than any maximum concentration listed for a specific nutrient in the profile.~~

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~~Minimum and some maximum nutrient concentrations were established in the Profiles for two categories; growth and reproduction (gestation/lactation), and adult maintenance. Maximum nutrient concentrations were established for nutrients where the potential for overuse or toxicity is of concern and likely to occur if attention is not paid to the concentrations of those nutrients. The absence of a maximum concentration should not be interpreted to mean that nutrients without a specific maximum content are safe~~

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~~at any concentration. Rather, it reflects the lack of information in dogs and cats on toxic concentrations of that nutrient. Establishing a maximum concentration implies safety below that concentration for long term consumption and to set a maximum arbitrarily might prove worse than no maximum at all.~~

~~The nutrient concentrations are expressed on a dry matter (DM) basis and at a specified caloric density. Diets should be corrected for caloric density as~~

~~indicated below. Reference to the concentrations of nutrients on a product label in the guaranteed analysis must be expressed in the same units and order as given in the AAFCO Dog or Cat Food Nutrient Profiles. For the purposes of determining metabolizable energy (ME), use the methods specified in Model Regulation PF9.~~

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From: Erickson, Jennifer [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=824E4C5933614C1ABBAECFB412746F84-JENNIFER.ER]
Sent: 12/16/2019 1:32:50 PM
To: Nelson, Eric [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f90377266c0c4a68bf8ac2b4783f8ac9-ENelson]
CC: McCoig, Amber [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=daa97064a98f4c249e0a1264311d1169-Amber.McCoi]
Subject: RE: Compliance Update Dec 10
Attachments: Compliance Update 10Dec2019.docx

Eric,
This is really helpful. Is it possibly to have Woody identify on his list who is the reg counsel for each of his cases going forward like the animal team does? It makes it easier for me to check in with my team then when things are looking like they are stalling.
Thanks,
Jen

From: McCoig, Amber <Amber.McCoig@fda.hhs.gov>
Sent: Tuesday, December 10, 2019 5:10 PM
To: Schell, Timothy <Timothy.Schell@fda.hhs.gov>; Groesbeck, Crystal <Crystal.Groesbeck@fda.hhs.gov>; Burnsteel, Cindy <Cindy.Burnsteel@fda.hhs.gov>
Cc: Nelson, Eric <Eric.Nelson@fda.hhs.gov>; Erickson, Jennifer <Jennifer.Erickson@fda.hhs.gov>
Subject: Compliance Update Dec 10

Good afternoon,
Please find the attached update on our current Post-Market Food and Drug cases. If you have any questions about specific cases, please feel free to reach out to me directly.
Kind Regards,
Amber

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(b) (4), (b) (5), (b) (7)(A)

(b) (4), (b) (5), (b) (7)(A)

(b) (4), (b) (5), (b) (7)(A)

(b) (4), (b) (5), (b) (7)(A)

[redacted]

(b) (4), (b) (5), (b) (7)(A)

From: Murphy, Jeanette [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=33924473C58F48519DA2CE0C7F8BA851-JMURPHY]
Sent: 12/18/2019 9:27:35 AM
To: Groesbeck, Crystal [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9b7c699402f743c3b747231cb9a1a4a4-CGroesbe]; Bair, Tonia [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=61b62fe2fb414fb2861003902258af2f-TBair]; Norris, Anne [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=891982b43d804c9396555baf36c73de1-Anne.Norris]; Steinberg, Nadine [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cc7979a0766747eaa65ea70be87fa51e-NSteinbe]; DeLancey, Siobhan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a414ba562dcd4c8284b1120074969b9a-SDELANCE]; Conway, Charlotte [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=93384ceea9df43b5b8dbc7d1fb58fe67-CConway]; Benjamin, Linda [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a259c40d1fe849d3bed7399e9cb099b1-LBENJAMI]; Nelson, Eric [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f90377266c0c4a68bf8ac2b4783f8ac9-ENelson]; Lambkin, Sonya [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7d0c915e0dbb4948914f8552e911f30f-Sonya.Lambk]; Reed-Jones, Neiunna [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ef52fce47e8c45898e7d0ead449313bc-Neiunna.Ree]; McCoig, Amber [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=daa97064a98f4c249e0a1264311d1169-Amber.McCoi]
CC: Schell, Timothy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c9a986a0fb324d12bcbe5dc0f4153330-Timothy.Sch]
Subject: RE: PiPF Status Check-in
Attachments: Retail Animal Food Safety

Greetings All,
The attached email will be one of our agenda items tomorrow.
Jenny

-----Original Appointment-----
From: Groesbeck, Crystal <Crystal.Groesbeck@fda.hhs.gov>
Sent: Monday, December 16, 2019 9:22 AM
To: Groesbeck, Crystal; Bair, Tonia; Norris, Anne; Steinberg, Nadine; Murphy, Jeanette; DeLancey, Siobhan; Conway, Charlotte; Benjamin, Linda; Nelson, Eric; Lambkin, Sonya; Reed-Jones, Neiunna; McCoig, Amber
Cc: Schell, Timothy
Subject: PiPF Status Check-in
When: Thursday, December 19, 2019 12:30 PM-1:00 PM (UTC-05:00) Eastern Time (US & Canada).
Where: WebEx

This time work best for most.
Thank you,
Crystal

-- Do not delete or change any of the following text. --

When it's time, join your Webex meeting here.

Meeting number (access code): (b) (6)

Meeting password: (b) (6)

Join meeting

Join by phone
Tap to call in from a mobile device (attendees only)
210-795-0506 US Toll
877-465-7975 US Toll Free
Global call-in numbers | Toll-free calling restrictions

If you are a host, go here to view host information.

Need help? Go to http://help.webex.com

From: Ferguson, Ashlee-Rose (AGR) [AFerguson@agr.wa.gov]
Sent: 12/13/2019 7:25:20 PM
To: Murphy, Jeanette [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=33924473c58f48519da2ce0c7f8ba851-JMURPHY]
Subject: Retail Animal Food Safety
Attachments: issue-pre-submission-form-2020_AFerguson-CreationOfACommittee.docx; Potential Language Updates_AFerguson.docx; Rationale_AFerguson.docx

Hey Jenny,

I hope you're doing well! Not sure if you remember from my IFPTI Fellowship Project presentation at the last AAFCO meeting, one of my recommendations to help reduce human foodborne illness caused by food for animals was to address it in the FDA Food Code. Not sure how familiar you are with the Food Code, but it is a model regulation that agencies can adopt to regulate food at the human food retail level. To make any changes to the Food Code, anyone can submit an issue at the Conference for Food Protection (CFP) which convenes every two years. The upcoming meeting is in Denver, March 30-April 1, 2020. I put together draft documents of what they're requiring with a recommendation to create a committee to evaluate if adding food for animals to the Food Code is a good/viable option. [I went with the term "food for animals" instead of "animal food" to reduce confusion with the "animal foods" definition in the 2017 Food Code which essentially means animal-derived foods.] I was wondering if the you would review the attachments to provide suggestions or anything. If CFP approves the creation of a committee, CVM involvement would be essential, as well as AAFCO. I hope to submit this Issue by Friday, Dec. 27th with the ability to make changes up to the deadline of Tuesday, Dec. 31st. Any response before then, hopefully by Friday Dec. 20th, would be greatly appreciated.

Moreover, this Issue would only address a sector of the retail industry, the human food establishments that hold animal food. To make sure prevention measures are consistent for the rest of that industry, the animal food establishments, language should be proposed in the AAFCO Model Bills and Regulations Committee. As a starting point for language, Seattle-King County Public Health has a had Zoonotic Disease Prevention Regulation (§8.03.290 to 8.03.310) that has addressed this issue since 2010. This could also close the loop hole for firms that utilize the direct to consumer retail exemption from FSMA.

I know this is short notice and a lot to consider but I think this will help reduce and prevent foodborne illness. I shared this with contacts in AFDO, the AAFCO Board, and conferred with a few FDA Retail Food Specialists. Please let me know if I should share this with anyone else or if you have any questions on anything.

Hope you have a great weekend and holiday season!

Ashlee-Rose Ferguson, RS
Program Coordinator** | **WSDA** | **Animal Feed Program
1111 Washington Street SE | PO Box 42560 | Olympia, WA 98504-2560
Mobile: 360-480-0498 | Desk: 360-902-1905 | Email: aferguson@agr.wa.gov

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WSDA Washington State Department of Agriculture | **Food Safety and Consumer Services Division**

Sign up for our new Listserv: WSDA-ANIMAL-FEED for a monthly newsletter!

WSDA Mission: Through service, regulation, and advocacy, the Washington State Department of Agriculture supports the viability and vitality of agriculture while protecting consumers, public health, and the environment.

Animal Feed Program Mission: We regulate the production and distribution of animal food to ensure its safety and integrity, in order to protect animal and public health and to ensure market fairness.

Please refer to the document titled "Issue Preparation & Review – Process & Checklist" for guidance.

Conference for Food Protection
2020 Biennial Meeting • Issue Submission Form

It is the policy of the Conference for Food Protection to not accept Issues that would endorse a brand name or a commercial proprietary process. Issues where brand names are used in the Issue, rationale, or solution will be rejected.

To provide guidance to Council in their preparation for Issue deliberation, please check if applicable:
☐ This Issue was submitted for consideration at a previous biennial meeting;
see Issue # ____________________ *(insert year and final assigned Issue number).*
  ☐ *New or additional information has been included or attached.*
  ☐ *Recommended Solution has been revised since previous submission.*

Title:

Creation of a Committee– Review of Food Code in relation to food for animals.

Issue you would like the Conference to consider:

Potential language updates in the Food Code to reduce human foodborne illness that is caused by food for animals. A thorough review of the Food Code is needed to determine if these potential updates could be effective in reducing and preventing human foodborne illness.

Public Health Significance:

It has been shown through whole-genome sequencing that human foodborne illness has been attributed to contaminated food for animals, shown in recent outbreaks. The same foodborne pathogens that can infect humans can contaminate food for animals and our exposure to our pet's food is only increasing. The changes that could result from this Issue would help ensure food for animals stored within human food establishments is stored and handled properly to prevent human foodborne illness.

Potential Impact:

Some components in the Food Code, such as in the Preface or Annexes, may need to be modified to account for potential language changes. Additional public health significance and potential regulatory or industry impacts are discussed within the Rationale document.

Recommended Solution:

The Conference recommends….

that a committee with all stakeholders be formed with the following charges:

1. Review and provide resolutions for the Potential Language Updates (attached);
2. Review all sections of the Food Code, including the Prefaces and Annexes, to determine if potential language updates would align with the current content and provide resolutions; and
3. Report back with findings and recommendations to the 2022 Conference Biennial Meeting.

Attachments:

Content Documents: *(documents requiring Council review; approval or acknowledgement is requested in the recommended solution above)*

- Potential Language Updates
- Rationale

Supporting Attachments: *(documents submitted to provide background information to Council)*

- IFPTI Fellowship Research Paper- "Refrigerated and Frozen Pet Food: Estimating Risk Factors and Analyzing Regulatory Authority": [HYPERLINK "https://ifpti.org/fellowship-program/published-works/refrigerated-and-frozen-pet-food-estimating-risk-factors-and-analyzing-regulatory-authority/"]

- The definition of "food" in the §321 of the Food, Drug, & Cosmetic Act: [HYPERLINK "https://uscode.house.gov/view.xhtml?path=/prelim@title21/chapter9&edition=prelim"]
- The definition of "food" in the §6 of Pure Food & Drug Act of 1906: [HYPERLINK "https://en.wikisource.org/wiki/Pure_Food_and_Drug_Act_of_1906"]
- [HYPERLINK "https://www.cdc.gov/"] to view current and previous human foodborne illness outbreaks that have identified food for animals as a source.
- [HYPERLINK "https://www.fda.gov/safety/recalls-market-withdrawals-safety-alerts"] to view recalls of food for animals contaminated with pathogens that can cause human foodborne illness.
- FDA- "Get the Facts! Raw Pet Food Diets can be Dangerous to You and Your Pet": [HYPERLINK "https://www.fda.gov/animal-veterinary/animal-health-literacy/get-facts-raw-pet-food-diets-can-be-dangerous-you-and-your-pet"]
- CDC- "Pet Food Safety": [HYPERLINK "https://www.cdc.gov/healthypets/publications/pet-food-safety.html"]

Submitter Information:

☒ I am a first time Issue submitter

NOTE: checking the "first time submitter" box will enable the assigned Council Chair to contact you in advance of the Biennial Meeting to answer any questions about the process involved in presenting an Issue to Council. Checking this box is for Council Chair information only and is NOT included in the final Issue document presented to Council.

Contact information entered below will remain with the final Issue submission posted and archived on the CFP website.

	Contact #1	***Contact #2***
Name	**Ashlee-Rose Ferguson**	
Organization	**WA State Department of Agriculture**	
Address *(line 1)*	**1111 Washington St SE**	
Address *(line 2)*		
City / State / Zip	**Olympia, WA 98504**	
E-mail	[HYPERLINK "mailto:aferguson@agr.wa.gov"]	
Telephone	**360-902-1905**	

Potential Language Updates

Creation of a Committee– Review of Food Code in relation to food for animals.

§1-201.10(B) of the most recent edition of the Food Code be amended as follows (new language underlined, deleted language strikeout)

"**Food**" means a raw, cooked, or processed edible substance, ice, BEVERAGE, or ingredient used or intended for use or for sale in whole or in part for human or other animal consumption, or chewing gum.

Food Establishment.

(1) "**Food establishment**" means an operation that:

(a) stores, prepares, packages, serves, vends food directly to the consumer, or otherwise provides FOOD for human consumption such as a restaurant; satellite or catered feeding location; catering operation if the operation provides FOOD directly to a CONSUMER or to a conveyance used to transport people; market; vending location; conveyance used to transport people; institution; ~~or~~ FOOD bank; or stores FOOD for animal consumption; and

(b) relinquishes possession of FOOD to a CONSUMER directly, or indirectly through a delivery service such as home delivery of grocery orders or restaurant takeout orders, or delivery service that is provided by common carriers.

(2) "**Food establishment**" includes:

(a) An element of the operation such as a transportation vehicle or a central preparation facility that supplies a vending location or satellite feeding location unless the vending or feeding location is permitted by the REGULATORY AUTHORITY; and

(b) An operation that is conducted in a mobile, stationary, temporary, or permanent facility or location; where consumption is on or off the PREMISES; and regardless of whether there is a charge for the FOOD.

(3) "**Food establishment**" does not include:

(a) An establishment that offers only prePACKAGED FOODS that are not TIME/TEMPERATURE CONTROL FOR SAFETY FOODS;

(b) A produce stand that only offers whole, uncut fresh fruits and vegetables;

(c) A FOOD PROCESSING PLANT; including those that are located on the PREMISES of a FOOD ESTABLISHMENT

(d) A kitchen in a private home if only FOOD that is not TIME/TEMPERATURE CONTROL FOR SAFETY FOOD, is prepared for sale or service at a function such as a religious or charitable organization's bake sale if allowed by LAW and if the CONSUMER is informed by a clearly visible placard at the sales or service location that the FOOD is prepared in a kitchen that is not subject to regulation and inspection by the REGULATORY AUTHORITY;

(e) An area where FOOD that is prepared as specified in Subparagraph (3)(d) of this definition is sold or offered for human consumption;

Potential Language Updates

Creation of a Committee– Review of Food Code in relation to food for animals.

(f) A kitchen in a private home, such as a small family day-care provider; or a bed-and-breakfast operation that prepares and offers FOOD to guests if the home is owner occupied, the number of available guest bedrooms does not exceed 6, breakfast is the only meal offered, the number of guests served does not exceed 18, and the CONSUMER is informed by statements contained in published advertisements, mailed brochures, and placards posted at the registration area that the FOOD is prepared in a kitchen that is not regulated and inspected by the REGULATORY AUTHORITY; ~~or~~

(g) A private home that receives catered or home-delivered FOOD~~.~~; or

(h) An establishment that offers FOOD for animal consumption or serves animals as their main function, such as a pet food retail business, a feed store, or a groomer.

(2) "**Ready-to-eat food**" includes:

(a) Raw animal FOOD that is cooked as specified under § 3-401.11 or 3-401.12, ~~or~~ frozen as specified under § 3-402.11, or uncooked or partially cooked if for animal consumption;

(b) Raw fruits and vegetables that are washed as specified under § 3-302.15;

(c) Fruits and vegetables that are cooked for hot holding, as specified under § 3-401.13;

(d) All TIME/TEMPERATURE CONTROL FOR SAFETY FOOD that is cooked to the temperature and time required for the specific FOOD under Subpart 3-401 and cooled as specified under § 3-501.14 or uncooked or partially cooked if for animal consumption;

(e) Plant FOOD for which further washing, cooking, or other processing is not required for FOOD safety, and from which rinds, peels, husks, or shells, if naturally present are removed;

(f) Substances derived from plants such as spices, seasonings, and sugar;

(g) A bakery item such as bread, cakes, pies, fillings, or icing for which further cooking is not required for FOOD safety;

(h) The following products that are produced in accordance with USDA guidelines and that have received a lethality treatment for pathogens: dry, fermented sausages, such as dry salami or pepperoni; salt-cured MEAT and POULTRY products, such as prosciutto ham, country cured ham, and Parma ham; and dried MEAT and POULTRY products, such as jerky or beef sticks; and

(i) FOODS manufactured as specified in 21 CFR Part 113, Thermally Processed Low-Acid Foods Packaged in Hermetically Sealed Containers.

Potential Language Updates

Creation of a Committee– Review of Food Code in relation to food for animals.

§3-306.11 and 3-306.13 of the most recent edition of the Food Code be amended as follows (new language underlined, deleted language strikeout)

Preventing Contamination by or to Consumers

3-306.11 Food Display.

(A) Except for nuts in the shell and whole, raw fruits and vegetables that are intended for hulling, peeling, or washing by the CONSUMER before consumption, FOOD on display shall be protected from contamination by the use of PACKAGING; counter, service line, or salad bar FOOD guards; display cases; or other effective means. ^{P}

(B) Exposed uncooked or partially cooked FOOD for animals on display shall be protected from direct access by ensuring that any open bins, baskets, or other open containers are out of reach of children. ^{P}

3-306.13 Consumer Self-Service Operations.

(A) Raw, unPACKAGED animal FOOD, such as beef, lamb, pork, POULTRY, and FISH may not be offered for CONSUMER self-service. ^{P}
This paragraph does not apply to:

(1) *CONSUMER self-service of READY-TO-EAT FOODS at buffets or salad bars that serve FOODS such as sushi or raw shellfish;*

(2) *Ready-to-cook individual portions for immediate cooking and consumption on the PREMISES such as CONSUMER-cooked MEATS or CONSUMER-selected ingredients for Mongolian barbecue;* ~~*or*~~

(3) *Raw, frozen, shell-on shrimp, or lobster~~.~~; or*

(4) *Uncooked or partially cooked FOOD for animal consumption such as but not limited to dried pet treats.*

(B) CONSUMER self-service operations for READY-TO-EAT FOODS or FOOD for animals shall be provided with suitable UTENSILS or effective dispensing methods that protect ~~the FOOD~~ from contamination. ^{Pf}

(C) CONSUMER self-service operations such as buffets and salad bars shall be monitored by FOOD EMPLOYEES trained in safe operating procedures. ^{Pf}

Rationale

Creation of a Committee– Review of Food Code in relation to food for animals.

Problem that needs to be addressed:

Human foodborne illness can be caused by food for animals. Several outbreaks with whole genome sequencing traceback have revealed food for animals as the source for human illness. A recent national human foodborne illness outbreak affecting 34 states with over 154 reported cases and 25 hospitalizations was traced back to pig ear pet treats. Twenty-seven cases were children younger than 5 years old. Examples of nationwide human foodborne illness contributed to contaminated pet food has been associated with both raw and dry pet food products. It is possible food for animals could have been a source for even more outbreaks in the past. Foodborne illness surveys used in epidemiological investigations typically have not addressed exposure to food for animals; therefore, an association may have been missed during previous investigations.

Additionally, food for animals is currently not regulated to prevent human foodborne illness at all levels throughout its entire supply chain. Consistent and collaborative regulation of food for animals may mitigate the associated risks. The same pathogens causing foodborne illness in humans are present in pet foods. Although the same safety measures apply, they are often overlooked when the products are intended for animals. Often consumers are handling animal pet foods in their own kitchens and simultaneously preparing human foods. Pet owners regularly handle their pet's foods and treats, and thereby unknowingly, or possibly unconsciously, expose themselves to potential foodborne pathogens.

Recalls of pet food for animals have been issued as a precaution as the products contain pathogen strains harmful to both humans and animals. While helpful, precautionary recalls are a reactive response to a problem where preventative measures exist. A unified, one health approach to prevention is necessary.

Cause of the problem:

The extent of the human-companion animal bond is undeniable and ever-growing. Humans are now viewing their pets as a member of their family. By default, humans have significantly more exposure to their pets' food. Food for animals can be found in thousands of establishments of varying types such as grocery stores, farmer's markets, and home improvement stores across the country. An explosion of new varieties of food for animals such as refrigerated and frozen pet food, are increasing in popularity and availability. Most animal food regulatory programs do not have the capacity to verify safety measures at even a fraction of these establishments nor do most have the training or tools required for time/temperature control for safety food for animals. A significant misperception may exist among consumers and regulators alike dismissing human foodborne illness caused by contaminated food for animals or how these two outwardly different worlds connect.

Why the status quo is not addressing the problem:

As stated above, the exponential expansion of the pet food market into traditional human food establishments has exceeded the resources of animal food regulatory programs. The regulatory focus has generally been at the manufacturing level. This has left less resources for the retail sector. Most animal food regulators are untrained in the requirements for time/temperature control for safety food for animals associated with refrigerated and frozen pet foods. Often they do not have the equipment, such as thermometers, to properly regulate risk factors associated.

Rationale

Creation of a Committee– Review of Food Code in relation to food for animals.

Science tells us proper cold holding and freezing significantly limits the exponential growth of bacteria. Also, proper handling and storage reduces risk of cross-contamination.

The Food Safety Modernization Act (FSMA) was enacted into law in 2011 with the main purpose to prevent adulteration. Since most animal food regulatory agencies adopt FSMA regulations and/or AAFCO (Association of American Feed Control Officials) Model Bill and Regulations there is very little safety measures existing for the retail sector since neither properly address known retail prevention measures. Furthermore, the Food Code does not address food for animals, even though the federal definition of “food” includes food for other animals since the definition’s inception in 1906 with the Pure Food and Drug Act.

Another goal of FSMA is to build and maintain an integrated food safety system with mutual reliance, essentially viewing public health through a one-health approach which recognizes that all components are interconnected. In the past, there has been limited collaboration between human food regulators and animal food regulators, resulting in silos and lack of awareness of how each type of food is regulated. Utilizing diverse expertise on both ends of the food spectrum, a unified approach to addressing food for animals in commerce could be enhanced to a level of prevention, mutual reliance, and in integrated food safety system; thus advancing the desired outcomes of FSMA.

Recommended policy solution:

In an effort to reduce or prevent human foodborne illnesses caused by food for animals, a creation of a diverse committee to review the Food Code and potential language updates, provide resolutions, and report back to the 2022 CFP Biennial Meeting is recommended. This committee would review the Food Code to reflect safety measures at the retail level for food for animals, specifically at human food establishments to help reduce or prevent human foodborne illness. Potential language updates have been provided as a starting point for this committee.

Potential consequences with recommendation:

Human food regulatory agencies will have to determine if their laws grant them authority to utilize the federal definition of food (Federal Food, Drug & Cosmetic Act, §321(f)) or if they have an equivalent definition. This would allow these agencies the proper authority if they were to adopt the new Food Code that contained the proposed changes. Otherwise, they would need to modify their law’s definition.

Human food regulators will likely only have an additional aisle to inspect when in the human food establishments; those that store food for animals. The proposed changes will only be applied to human food regulator’s existing inventory. Grocery stores, being the most likely example, are already accustomed to this type of regulation; however, the product companies may not be as familiar with retail regulation. Outreach and inclusion of the animal food industry is needed. To ensure equivalent and consistent regulation on the retail level, language updates will be proposed to AAFCO Model Bills and Regulations Committee for retail animal food establishments.

From: Nelson, Eric [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=F90377266C0C4A68BF8AC2B4783F8AC9-ENELSON]
Sent: 12/11/2019 9:49:30 AM
To: Erickson, Jennifer [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=824e4c5933614c1abbaecfb412746f84-Jennifer.Er]
CC: Schell, Timothy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c9a986a0fb324d12bcbe5dc0f4153330-Timothy.Sch]
Subject: Talking points for FDLI
Attachments: FDLI Enforcement Cnf 12-19 TPs for Eric.docx; [redacted] (b) (5) for FDLI Enforcement.docx

Sorry Jen, I email the chair yesterday and said see you on Thursday. I had it scheduled for tomorrow.

Eric M Nelson
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Clearance Legend

Drafted: JErickson 12/2/19

Reviewed: JMurphy 12/3/19

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From: Erickson, Jennifer [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=824E4C5933614C1ABBAECFB412746F84-JENNIFER.ER]
Sent: 12/12/2019 2:08:19 PM
To: Edwards, David [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=df3e3d2ae5ab4c7dabec7ecea8a82404-David.Edwar]; Conway, Charlotte [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=93384ceea9df43b5b8dbc7d1fb58fe67-CConway]; McCoig, Amber [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=daa97064a98f4c249e0a1264311d1169-Amber.McCoi]; Nelson, Eric [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f90377266c0c4a68bf8ac2b4783f8ac9-ENelson]; Groesbeck, Crystal [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9b7c699402f743c3b747231cb9a1a4a4-CGroesbe]; Murphy, Jeanette [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=33924473c58f48519da2ce0c7f8ba851-JMURPHY]
CC: Sklenka, Sara [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=37d065be7d554b33a8215db9a6c9e51b-SSklenka]; Henry, Michael H [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=de0157e03fc84589b811912fdf678fc3-MHENRY1]; Benjamin, Linda [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a259c40d1fe849d3bed7399e9cb099b1-LBENJAMI]; Orr, Adam [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=826fa6508c0d4f89bddec1e628085d6f-AOrr]; Jordre, Shannon [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=43f838419e224a07915e3c10fd053a4d-SJordre]; Johnston, Ying F [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e3a3d4fa0d9d4db7960decf196c9ed5a-YJohnston]
Subject: Diverson/Reconditioning GFI - division clearance
Attachments: GFI XXX Reconditioning and Diversion for Use as Animal Food 12.21.18.docx

Good afternoon!
The moment you have been waiting over a year for …. We have worked diligently to address your comments and the diversion and reconditioning guidance is ready for your clearance. Sorry for how long it took, (b) (5) .

Here is the link to review and provide your division clearance: GFI XXX Reconditioning and Diversion for Use as Animal Food 12.12.19_clean for OSC review. I think the next step after that will be the formal OSC clearance process. For your reference, attached is last years versions with your comments and our edits in track-changes in case if you want to peak back and/or see our reasoning in response to your comments.

Let me know if you have any questions,
Thanks,
Jen

Jennifer Erickson
Acting Regulatory Counsel Team Lead

Center for Veterinary Medicine (CVM)
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From: Murphy, Jeanette [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=33924473C58F48519DA2CE0C7F8BA851-JMURPHY]
Sent: 12/5/2019 5:25:19 PM
To: Conway, Charlotte [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=93384ceea9df43b5b8dbc7d1fb58fe67-CConway]; Lambkin, Sonya [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7d0c915e0dbb4948914f8552e911f30f-Sonya.Lambk]; Bair, Tonia [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=61b62fe2fb414fb2861003902258af2f-TBair]; Hartogensis, Martine [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=02df91d554d34b948fc58433d0e42073-MHARTOGE]; Palmer, Lee Anne [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cf7c8bd53b6c45a39318a596acea7c53-LPALMER]; Hodges, April [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2f96eb3112ef4669ae2aee02766538ff-April.Hodge]
CC: Nelson, Eric [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f90377266c0c4a68bf8ac2b4783f8ac9-ENelson]; Keller, Marla [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cc6adb77a41a4eeab3de9513feee0bd9-MLuther]; Groesbeck, Crystal [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9b7c699402f743c3b747231cb9a1a4a4-CGroesbe]; Oehlsen, Michael [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c40f6cd6f8414fee96986a1b9b009162-MOEHLSEN]; McCoig, Amber [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=daa97064a98f4c249e0a1264311d1169-Amber.McCoi]
Subject: Help: Need input on questions from the gov't of Japan
Attachments: 12-20-11 CVM Annual Report Draft 2 _clean.docx

Greetings All,

Marla, Sonya, and I recently met with representatives for the government of Japan. (b) (5)
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We met with them on Tuesday and agreed to subsequently complete the attached questionnaire.

We discussed some of these topics at a high level during the meeting but now is time to provide a more formal response. Marla and I have taken a stab at drafting responses to most questions but need help/input from you all to finish. I have flagged questions for each of you.

(b) (5)

Feel free to kick these to other members of your staff to answer.
Would it be possible for a response **by 12/12/19**?

Send your edits/comments to Marla (and cc me and Crystal).

Thanks,

Jenny and Marla
Jenny Murphy
Office of Surveillance and Compliance
Center for Veterinary Medicine
7519 Standish Place
Rockville, MD 20855
Telephone: 240-402-6246
Email: jenny.murphy@fda.hhs.gov

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Department of Health and Human Services

Food and Drug Administration

21 CFR Parts 16, 225, 500 et al.

Current Good Manufacturing Practice and Hazard Analysis and Risk-Based Preventive Controls for Food for Animals; Proposed Rule

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 16, 225, 500, 507, and 579

[Docket No. FDA–2011–N–0922]

RIN 0910–AG10

Current Good Manufacturing Practice and Hazard Analysis and Risk-Based Preventive Controls for Food for Animals

AGENCY: Food and Drug Administration, HHS.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is proposing regulations for domestic and foreign facilities that are required to register under the Federal Food, Drug, and Cosmetic Act (the FD&C Act) to establish requirements for current good manufacturing practice in manufacturing, processing, packing, and holding of animal food. FDA also is proposing regulations to require that certain facilities establish and implement hazard analysis and risk-based preventive controls for food for animals. FDA is taking this action to provide greater assurance that animal food is safe and will not cause illness or injury to animals or humans and is intended to build an animal food safety system for the future that makes modern, science and risk-based preventive controls the norm across all sectors of the animal food system.

DATES: Submit either electronic or written comments on the proposed rule by February 26, 2014. Submit comments on information collection issues under the Paperwork Reduction Act of 1995 by November 29, 2013 (see the "Paperwork Reduction Act of 1995" section of this document).

ADDRESSES: You may submit comments, identified by Docket No. FDA–2011–N–0922 and/or Regulatory Information Number (RIN) 0910–AG10 by any of the following methods, except that comments on information collection issues under the Paperwork Reduction Act of 1995 must be submitted to the Office of Information and Regulatory Affairs, Office of Management and Budget (OMB) (see the "Paperwork Reduction Act of 1995" section of this document).

Electronic Submissions

Submit electronic comments in the following way:

- Federal eRulemaking Portal: *http://www.regulations.gov*. Follow the instructions for submitting comments.

Written Submissions

Submit written submissions in the following ways:

- Mail/Hand delivery/Courier (for paper or CD–ROM submissions): Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

Instructions: All submissions received must include the Agency name and Docket No 2011–N–0922 and RIN 0910–AG10 for this rulemaking. All comments received may be posted without change to *http://www.regulations.gov*, including any personal information provided. For additional information on submitting comments, see the "Comments" heading of the **SUPPLEMENTARY INFORMATION** section of this document.

Docket: For access to the docket to read background documents or comments received, go to *http://www.regulations.gov* and insert the docket number, found in brackets in the heading of this document, into the "Search" box and follow the prompts and/or go to the Division of Dockets Management, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Kim Young, Center for Veterinary Medicine (HFV–230), Food and Drug Administration, 7519 Standish Pl., Rockville, MD 20855, 240–276–9207, email: *kim.young@fda.hhs.gov*.

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Executive Summary

Purpose and Coverage of the Proposed Rule

The proposed rule would establish regulations regarding the manufacturing, processing, packing, or holding of animal food in two ways. First, it would create new current good manufacturing practice (CGMP) regulations that specifically address the manufacturing, processing, packing, and holding of animal food. Second, it would include new preventive control provisions intended to implement section 103 of the FDA Food Safety Modernization Act (FSMA) for animal food. In general, with some exceptions the new preventive control provisions would apply to animal food facilities that are required to register with FDA under FDA's current food facility registration regulations. These preventive controls would include requirements for covered facilities to maintain a food safety plan, perform a hazard analysis, and institute preventive controls for the mitigation of those hazards. Facilities would also be required to monitor their controls, verify that they were effective, take any appropriate corrective actions, and maintain records documenting these actions.

To put these changes in context, and to provide legal, regulatory, scientific, and technical information relevant to the new provisions, the Agency provides several sections of background. This background discusses the current approaches to animal food safety; summarizes the Food and Drug Administration Amendments Act of 2007 (FDAAA) as it applies to pet food; provides an overview of the provisions of FSMA applicable to this proposed rule; and describes a variety of hazards that have been associated with animal foods and animal food safety problems (including outbreaks of foodborne illness) that have resulted from these hazards. An Appendix also describes the role of testing as a verification measure in a food safety system and the role of supplier approval and verification programs in a food safety system.

Summary of the Major Provisions of the Proposed Rule

The proposed rule would establish certain CGMP provisions to ensure the safety and suitability of animal food. The implementation of these practices and procedures would protect against the contamination of animal food. The proposed CGMPs would establish procedures in areas such as buildings and facilities, design and layout, cleaning and maintenance, pest control, and personnel hygiene.

The proposed rule also would implement the requirements of section 103 of FSMA for animal food facilities that must register under section 415 of the FD&C Act (21 U.S.C. 350d) to establish and implement a food safety system that includes a hazard analysis and risk-based preventive controls. Specifically, the proposed rule would establish requirements for:

- A written food safety plan;
- Hazard analysis;
- Preventive controls for hazards that are reasonably likely to occur;
- Monitoring;
- Corrective actions;
- Verification; and
- Associated records.

The application of the preventive controls would be required only in cases where facilities determine that hazards are reasonably likely to occur. The Agency does not expect that all possible preventive measures and verification procedures would be applied to all animal foods at all facilities.

The proposed rule would also establish a series of exemptions (including modified requirements in some cases) from the requirements for hazard analysis and preventive controls. Facilities that manufacture, process, pack, or hold animal food and that are required to register with FDA under section 415 of the FD&C Act would be required to comply with the proposed regulation unless they are covered by an exemption. The table immediately below summarizes these proposed exemptions in general terms. Importantly, the table in this Executive Summary does not include all the details that a facility must consider to determine whether an exemption applies. The Agency provides those details in the proposed rule (proposed § 507.5) and explains them in section VIII.C.

PROPOSED EXEMPTIONS FROM THE NEW REQUIREMENTS FOR HAZARD ANALYSIS AND RISK-BASED PREVENTIVE CONTROLS

Who or what would be exempt from the requirements for hazard analysis and risk-based preventive controls	Notes
"Qualified Facility" as defined by FSMA • Business with average annual sales of <$500,000 and at least half the sales to consumers or local retailers or restaurants (within the same state or within 275 miles); or • Very small business ○ Option 1: Total annual sales of <$500,000 ○ Option 2: Total annual sales of <$1,000,000 ○ Option 3: Total annual sales of <$2,500,000	FDA is proposing three options for defining "very small business" and requests comment on which to adopt in a final rule. Modified requirements would apply—i.e., a qualified facility would be required to: • Notify FDA about its status; and • Either: ○ Notify FDA that it is addressing hazards through preventive controls and monitoring; or ○ Notify FDA that it complies with applicable local regulations, and notify consumers of the name and complete business address of the facility where the animal food was manufactured or processed.
• Low risk, on farm activities performed by a small business (<500 employees): or • Low-risk, on-farm activities performed by a very small business ○ Option 1: very small = <$500,000 ○ Option 2: very small = <$1,000,000 ○ Option 3: very small = <$2,500,000	Small and very small on-farm businesses conducting these low risk activities would be exempt from most of the rule's requirements. The Agency would define the low-risk activities that qualify for the exemption, including the specific foods to which they relate (such as re-packing intact fruits and vegetables, or grinding/milling/cracking/crushing grains).
Activities that are subject to the "low-acid canned food" requirements of § 500.23 (21 CFR 500.23) and part 113 (21 CFR part 113)	• The exemption applies only with respect to microbiological hazards. • The facility must be in compliance with part 113.
Activities of a facility that are subject to section 419 of the FD&C Act (21 U.S.C. 350h) (Standards for Produce Safety)	Published in the **Federal Register** January 16, 2013 (78 FR 3504).
Facilities that are solely engaged in the storage of raw agricultural commodities (other than fruits and vegetables) intended for further distribution or processing	A facility that stores raw agricultural commodities that are fruits or vegetables would not be exempt.
Facilities solely engaged in the storage of packaged animal food that is not exposed to the environment	Modified requirements would apply for the storage of refrigerated packaged animal food.

The proposed rule also would establish the conditions under which an exemption granted to a "qualified facility" could be withdrawn, and the procedures that would be followed to withdraw such an exemption. The proposed rule would establish requirements that would apply to all records that would be required by the various proposed provisions. The proposed recordkeeping provisions would implement specific requirements of FSMA regarding records associated with the new provisions for hazard analysis and risk-based preventive controls and would allow facilities to show, and FDA to determine, compliance with the regulatory requirements.

The proposed rule would require that a qualified individual prepare the food safety plan, validate preventive controls, review records for implementation and effectiveness of preventive controls and the appropriateness of corrective actions, and perform the required reanalysis of a food safety plan. The proposed rule also would establish minimum requirements for the "qualified individual," who would be required to successfully complete training with a standardized curriculum or be otherwise qualified through job experience to develop and apply a food safety system. Only a trained individual or individual qualified by job experience is capable of effectively executing these activities.

FDA is requesting comment on when and how other elements of a preventive controls system are an appropriate means of implementing the statutory directives, including: A product testing program, an environmental monitoring program, and a supplier approval and verification program, as appropriate.

Costs and Benefits

The summary of the costs and potential benefits of the proposed rule are presented in the table that follows.

	Total domestic costs annualized at 7 per cent over 10 years (millions)
Proposed Rule with Very Small Business Defined as Less Than or Equal to $500,000 in Annual Revenue	$95
Proposed Rule with Very Small Business Defined as Less Than or Equal to $1,000,000 in Annual Revenue	89
Proposed Rule with Very Small Business Defined as Less Than or Equal to $2,500,000 in Annual Revenue	65

I. Introduction

On January 4, 2011, President Obama signed into law the FDA Food Safety Modernization Act (FSMA) (Pub. L. 111–353). This law enables FDA to better protect public health by helping to ensure the safety and security of the human and animal food supply. FSMA enables the Agency to focus more on preventing food safety problems rather than relying primarily on reacting to problems after they occur. The law also provides the Agency with new enforcement authorities to help achieve higher rates of compliance with risk-based, prevention-oriented safety standards and to better respond to and contain problems when they do occur. In addition, the law gives the Agency important new tools to better ensure the safety of imported human and animal foods and directs the Agency to build an integrated national food safety system in partnership with State, local, tribal, and territorial authorities.

This new law continues efforts by the human and animal food industries and government to protect and improve the safety of the nation's food supply. At the Federal level, these efforts go back to the Pure Food and Drug Act of 1906, the United States' first national food safety law. FSMA carries forward the basic principle embodied in the 1906 law that food establishments have the primary responsibility and capacity to make food safe and that government's role is to set standards for food safety and provide oversight to help ensure standards are met.

Since passage of the 1906 Act, and the most recent revision of its basic food safety provisions in the Federal Food, Drug, and Cosmetic Act of 1938, the combined efforts of the food industry and government have produced a set of standards and practices that make the U.S. food supply among the safest in the world. These efforts include the development and adoption by FDA of CGMP standards for human food that have long provided the regulatory foundation for human food safety. They also include, in more recent years, the adoption for some elements of the animal and human food supply of more targeted, risk-based approaches, such as embodied in the Hazard Analysis and Critical Control Points (HACCP) approach to food safety.

HACCP was pioneered by the human food industry and reflects the understanding that food safety is best assured if each producer and processor understands the hazards that are reasonably likely to occur in their particular product and operation and puts in place scientifically sound preventive controls to significantly minimize or eliminate the hazard. FDA has by regulation required seafood and juice processors to implement the HACCP approach to preventive controls. The U.S. Department of Agriculture (USDA) has also mandated HACCP for meat and poultry processors, and many human food companies have implemented such modern preventive control systems for other commodities.

While these efforts have contributed to progress on food safety, significant human and animal food safety challenges persist in today's complex, dynamic, and global food system. Today's food supply is highly diverse and increasingly complex, with many new foods in the marketplace that pose new food safety challenges. New pathogens are emerging, and the Agency is seeing commonly known pathogens appear in foods where they have not been traditionally seen. The population of individuals at greater risk for foodborne illness, such as those who are immune-compromised, is increasing. When illness outbreaks occur, they can have devastating impacts on public health and impose substantial economic disruption and cost on the human and animal food industry. The food safety challenge is only compounded by globalization and the increasing amount of imported human and animal food.

Congress responded to today's food safety challenges by enacting FSMA. FSMA builds on past experience and the strong foundation provided by the current food safety system, but it also marks an historic turning point for food safety. FSMA directs FDA to build a food safety system for the future that makes modern, science- and risk-based preventive controls the norm across all sectors of the food system; meets the food safety challenges of the global food system; and establishes stronger partnerships for food safety across all levels of government and with the private sector to ensure optimal use of public and private resources. FDA has embarked on a comprehensive effort to build the food safety system mandated by Congress, as described on its FSMA implementation Web page at *http://www.fda.gov/fsma.*

A top priority for FDA are those FSMA-required regulations that provide the framework for industry's implementation of preventive controls and FDA's ability to oversee their implementation for both domestic and imported food. These include, among others, regulations establishing preventive control standards for human food and animal food facilities, produce safety standards, standards that define the accountability of importers to verify the safety of food produced overseas, and a new program for accrediting private bodies to provide credible certifications that regulated entities are meeting U.S. safety standards. A proposed rule on foreign supplier verification is closely interconnected to this rule on preventive controls for animal food (and the preventive controls proposed rule for human food), and published in the **Federal Register** on July 29, 2013 (78 FR 45730).

In this document, the Agency proposes standards to implement the requirement in section 103 of FSMA for the adoption of preventive controls in animal food facilities. This preamble provides information on FDA's previous efforts in working to establish CGMPs and process controls for animal food, because these past efforts are the critical starting point and foundation for FSMA implementation. The preamble explains and provides additional background on the rationale for the Agency's proposed regulations implementing FSMA's preventive controls requirement and new CGMPs for the animal food industry. The Agency is seeking comments on all aspects of this proposal.

The document for the proposed rule for preventive controls for human food, published in the **Federal Register** January 16, 2013 (78 FR 3646), contains discussions that are relevant to animal food safety and the development of preventive controls for food for animals. The Agency has identified relevant discussion found in the human food preamble throughout this preamble and references the published document for proposed preventive controls for human food for additional information.

II. Background

Ensuring the safety of animal food is complex in light of several factors. Animal food is made for a wide variety of species, including animals from which human foods are derived, pet animals, and laboratory animals. Many animals consume one food as their sole source of nutrition. Therefore, the food that they consume must be nutritionally adequate or the food presents a safety hazard to the animals. Nutrient deficiencies or excesses can raise safety concerns. Because different species have different nutritional needs, certain quantities of a nutrient that are needed by one species of animal could pose a health risk to another species of animal. Therefore, safety issues for animal food can be raised not only by biological, chemical, physical, or radiological contaminates of the food that can cause animal or human health concerns, but also by nutrient deficiencies (or excesses) for the animals.

Animal foods are also handled in a wide variety of settings. Some foods are handled on farms or in feed mills. Other foods, like pet foods, are handled in homes and often in the kitchen. If the pet food is contaminated with a pathogen of human health concern, this could result in secondary contamination of human food-contact surfaces or human food. Humans could become ill from the pathogen through handling the pet food or through these secondary contaminations.

The discussion that follows explains current regulatory tools and other approaches the Agency has explored to address the safety of animal food for animals, the safety of food from food-producing animals consumed by humans, and the safety of humans handling animal food.

This proposed rule would implement needed controls for animal food. This proposed rule would also help respond to requests the Agency receives from international standard-setting organizations (e.g., Codex Alimentarius) and individual countries that ask feed-exporting countries to operate animal food safety systems with clear regulatory oversight.

A. Current Approaches to Animal Food Safety

1. Animal Feed Safety System Working Group

The Agency's efforts to upgrade animal food safety in this country are continually evolving. Historically, FDA's animal food program focused on specific safety issues, such as unsafe tissue residues resulting from feeding of medicated animal food, Bovine Spongiform Encephalopathy (BSE), and *Salmonella,* but had not addressed animal food safety in a comprehensive manner. In 2003, FDA introduced the concept of an Animal Feed Safety System (AFSS). A working group, the AFSS Working Group, was established and charged with reviewing the many separate regulations and supporting programs related to regulation of animal food by FDA and the States, and identifying gaps in the regulation of animal food that need to be addressed. The goal of this working group was, and remains, the development and implementation of a comprehensive, risk-based program that describes how all animal food (individual ingredients and mixtures of ingredients) should be manufactured and distributed to ensure the safety of the food for animal consumption, as well as the safety of human food derived from these animals (e.g., meat, milk, and eggs). The working group's concept for an AFSS covers the entire continuum of Agency activities including:

- Pre-approval of additives for use in animal food;
- Establishing limits for hazards in animal food;
- Providing education and training;
- Conducting research;
- Performing inspections;
- Taking enforcement for ensuring compliance with Agency regulations; and
- Establishing partnerships with State regulators with responsibility for animal food safety.

The AFSS concept also includes oversight of animal food production, including manufacture, labeling, storage, distribution and use of all animal food at all stages of production and use. A key element of the AFSS concept is a systems approach that includes best management practices during the "manufacturing, labeling, storage, and distribution" of all animal food, coupled with steps to identify hazards and to minimize or eliminate, as appropriate, the occurrence of those hazards.

The AFSS Working Group held public meetings on the AFSS concept in September 2003 and April 2005. The meetings were designed primarily to give stakeholders an opportunity to present information to FDA about the direction and scope of the AFSS. Three additional meetings, held in September 2006, May 2007, and May 2008, informed stakeholders of the risk assessment initiatives being undertaken by the AFSS Working Group. Information on these meetings can be found at the Agency's Web site (Ref. 1).

The AFSS Working Group used a number of sources in developing its current design of components comprising the AFSS, including comments from the public solicited through public meetings and interactions with State regulatory officials, industry representatives, veterinarians and consumers. In addition, the working group reviewed some of the approaches used by the Agency and by industry to ensure human food safety, such as HACCP systems, Standard Operating Procedures (SOPs), Sanitation Standard Operating Procedures (SSOPs), and CGMPs, to determine their applicability and usefulness to animal food control and regulatory oversight in a risk-based preventive system. The working group also reviewed the Codex Code of Practice on Good Animal Feeding as a comparison to help identify gaps in the Agency's current regulatory approach to animal food safety (Ref. 2). The Codex Code was accepted by the European Union along with other foreign entities and the U.S. delegation, which was comprised of U.S. Federal and State Government officials and industry advisors to the Codex's Task Force on Good Animal Feeding Practices.

The AFSS Working Group identified seven operating components to comprise the AFSS. These components cover processes to ensure that:

- Ingredients used in animal food are safe;
- The methods used to make, store, and distribute animal food result in safe products;
- The Agency acquires timely information about unsafe animal food and, when appropriate, makes such information publicly available;
- The levels of regulatory oversight are commensurate with risk to human and animal health;
- Training, education, and outreach activities keep the Agency's partners and stakeholders well informed and ensure that the Agency and State animal food regulatory personnel are adequately trained; and
- An active and aggressive research program is employed to generate data to aid in addressing animal food safety issues.

With the assistance of regulated animal food industry, the public, and State regulatory personnel, the working group identified gaps in the regulation of labeling, processing, and distribution of animal food products. The working group describes these gaps and ways to address them in the fourth AFSS Framework Document dated January 2010, which can be found on FDA's Web site (Ref. 3).

One critical gap is the lack of Federal regulations to fully address all aspects of producing safe animal food associated with the receiving, manufacturing, processing, packing, holding and distribution of animal food (including pet food, animal feed, and raw materials and ingredients) that does not contain animal drugs (i.e., non-medicated animal food). To fill this gap, the working group began developing a process control standards proposed rule, which aimed to prevent, eliminate, or reduce to acceptable levels the potential risks posed to human and animal health through a systems approach in which adequate control steps would be established throughout the animal food manufacturing process. After the passage of FSMA, the Agency incorporated the work begun on the proposed rule for process control standards into this proposed rule for preventive controls for animal food.

In addition, the AFSS Working Group is developing and systematically applying a method that ranks risks associated with all identified hazards. The use of risk concepts is not new for the Agency, as FDA routinely tries to estimate public health impact in deciding where to focus regulatory effort in general. The Agency relies heavily on evaluation of risk posed by hazards that occur in animal food when making decisions about food safety. Information on the AFSS can be found at the Agency's Web site (Ref. 4).

2. Section 402 of the FD&C Act

Section 402 of the FD&C Act (21 U.S.C. 342) deems food, including animal food, adulterated in several circumstances, including:

a. If it bears or contains any poisonous or deleterious substance which may render it injurious to health (section 402(a)(1));

b. If it bears or contains a pesticide chemical residue that is unsafe within the meaning of section 408(a) of the FD&C Act (21 U.S.C. 346a) (section 402(a)(2)(B));

c. If it bears or contains an unapproved food additive or an unapproved new animal drug (section 402(a)(2)(C));

d. If it consists in whole or in part of any filthy, putrid, or decomposed substance, or if it is otherwise unfit for food (section 402(a)(3)); and

e. If it has been prepared, packed, or held under insanitary conditions whereby it may have become contaminated with filth, or whereby it may have been rendered injurious to health (section 402(a)(4)).

While the Agency has issued regulations related to the safety of specific types of animal food and the use of certain food substances in animal food, as will be described further in this preamble, section 402 of the FD&C Act applies to all animal food in interstate commerce.

3. Thermally Processed Low-Acid Foods Packaged in Hermetically Sealed Containers (LACF)

Animal foods that are thermally processed low-acid foods packaged in hermetically sealed containers are subject to the regulations in 21 CFR 500.23, which in turn states the provisions of part 113 (21 CFR part 113) applies to animal food. Part 113 establishes the criteria by which FDA determines whether the facilities, methods, practices, and controls used by the commercial processor in the manufacture, processing, or packing of low-acid foods in hermetically sealed containers are operated or administered in a manner adequate to protect the public health.

4. Animal Proteins Prohibited From Use in Animal Feeds

The regulation in § 589.2000 (21 CFR 589.2000), prohibiting the use of certain animal proteins in ruminant feed, was published on June 5, 1997 (62 FR 30936). It was designed to prevent the establishment and amplification of BSE, through animal food, by prohibiting the use of certain proteins derived from mammalian tissue in the feeding of ruminant animals. This BSE regulation affects renderers, protein blenders, commercial animal food manufacturers, distributors (including retailers), transporters of animal food and ingredients, on-farm animal food mixers, and ruminant feeders.

On December 7, 2000, the USDA/Animal and Plant Health Inspection Service (USDA/APHIS) enacted regulations prohibiting the importation into the United States of all meat and bone meal (MBM), meat meal, bone meal, blood meal, tankage, offal, tallow, or any product containing such, which originated directly from countries identified as having BSE, or from countries having inadequate systems in place to prevent BSE (9 CFR 94.18 and 95.4). The prohibitions include all rendered products of animal origin including poultry meal and fishmeal that are processed in these countries, regardless of species of origin, unless the material is from a non-ruminant species and meets certain conditions assuring no contamination with ruminant material. These prohibitions were deemed necessary by APHIS because of the possibility of cross contamination with the BSE agent. Subsequently, on January 20, 2001, FDA issued Import Alert #99–25, "Detention Without Physical Examination of Animal Feed, Animal Feed Ingredients and Other Products for Animal Use Consisting or Containing Ingredients of Animal Origin" (Ref. 5).

On April 25, 2008, FDA published a final rule in the **Federal Register**, amending the BSE regulations to prohibit the use of certain cattle origin material in the food or feed of all animals (73 FR 22720). This final rule established new regulations entitled "Cattle Materials Prohibited in Animal Food or Feed to Prevent the Transmission of Bovine Spongiform Encephalopathy". The new regulation, § 589.2001 (21 CFR 589.2001), prohibits the use of certain cattle materials in the feed of all animals and is aimed primarily at rendering operations. This new rule also amended the BSE regulation in 21 CFR 589.2000.

FDA assesses compliance of the BSE regulations through the Agency's BSE/Ruminant Feed Ban Inspection Program (7371.009) (Ref. 6). This program is designed to assess an animal food facility's operational practices and procedures in preventing the spread of BSE through inspectional observations and sampling.

5. Medicated Feeds CGMP

Section 501(a)(2)(B) of the FD&C Act (21 U.S.C. 351(a)(2)(B)) provides that a drug (including a drug contained in a medicated feed) shall be deemed to be adulterated if the methods used in, or the facilities or controls used for, its manufacture, processing, packing, or holding do not conform to or are not operated or administered in conformity with current good manufacturing practice to assure that such drug meets the requirement of the FD&C Act as to safety, and has the identity and strength, and meets the quality and purity characteristics, which it purports or is represented to possess.

In May 1965, the Agency issued Current Good Manufacturing Practice for Medicated Feeds, which implemented section 501(a)(2)(B) of the FD&C Act for medicated animal food (30 FR 6475). The purpose of this medicated feed regulation, part 225 (21 CFR part 225), was to establish specific criteria for CGMPs that would ensure the safety, identity, strength, and the quality and purity characteristics of medicated feed. Medicated feed that is not manufactured, processed, packed, or held in conformity with part 225 is adulterated under section 501(a)(2)(B) of the FD&C Act.

The medicated feed CGMPs ensure a pure, safe drug product through requiring specific preventive measures during manufacturing, processing, packing, and holding. In general, the CGMPs in part 225 do not apply to the manufacturing, processing, packing, and holding of non-medicated animal food, even if manufactured in the same facility. However, non-medicated feed would be deemed adulterated under section 402(a)(2)(C)(ii) of the FD&C Act if contaminated with a new animal drug.

6. Animal Food Labeling

FDA regulations that establish animal food labeling standards in part 501 (21 CFR part 501) include requirements for a statement of identity, net quantity statement, manufacturer's name and address, and proper listing of ingredients. In addition, the FDAAA required FDA to issue regulations to update the standards for pet food labeling. These implementing regulations are currently being developed by FDA. Further discussion of FDAAA is presented in section II.B.

7. Generally Accepted as Safe (GRAS) Lists and GRAS Notifications

GRAS is an acronym for the phrase Generally Recognized as Safe. Under section 201(s) of the FD&C Act (21 U.S.C. 321(s)), a substance is not a food additive if it is generally recognized, among qualified experts, as having been adequately shown to be safe under the conditions of its intended use, or unless the use of the substance is otherwise excluded from the definition of a food additive. A listing of substances that are considered by the Agency to be generally recognized as safe for specific intended uses in animal food is found in 21 CFR parts 582 and 584.

Under section 201(s) of the FD&C Act and 21 CFR 570.30, a substance may be deemed to be GRAS if it is generally recognized as having been adequately shown to be safe under the conditions of its intended use in food through scientific procedures or, for a substance used in food before 1958, through experience based on common use in food.

A GRAS substance is not subject to premarket review and approval by FDA. A firm may market a GRAS substance intended for use in animal food based on its own determination that the intended use is GRAS. If the intended use of the substance is not GRAS, the substance and firm marketing it for this use may be subject to enforcement action by FDA.

Although not required to do so, firms that have determined that the intended use of a substance in animal food is GRAS may petition FDA to affirm that a substance is GRAS under certain conditions of use under 21 CFR 570.35(c). Alternatively, they may participate in FDA's GRAS notification pilot program. On June 4, 2010, FDA announced that it would begin a voluntary pilot program for GRAS notifications for substances added to animal food (75 FR 31800). This program is based on an April 17, 1997 proposed rule on GRAS notification (62 FR 18938).

8. Approved Food Additives

Under section 201(s) of the FD&C Act, a food additive means "any substance the intended use of which results or may reasonably be expected to result, directly or indirectly, in its becoming a component or otherwise affecting the characteristics of any food (including any substance intended for use in producing, manufacturing, packing, processing, preparing, treating, packaging, transporting, or holding food; and including any source of radiation intended for any such use), if such substance is not generally recognized, among experts qualified by scientific training and experience to evaluate its safety, as having been adequately shown through scientific procedures (or in the case of a substance used in food prior to January 1, 1958, through scientific procedures or experience based on common use in food) to be safe under the conditions of its intended use. . .". Other substances that are excluded from the definition of a food additive include pesticide chemical residues, pesticide chemicals, color additives, prior sanctioned substances, and new animal drugs.

Many substances added to an animal food are food additives, varying by composition and intended use. A food additive generally provides one or more of the following attributes: nutrition, aroma/flavor, stabilization, emulsification, and preservation. A listing of food additives permitted in animal food, including drinking water for animals, is found in 21 CFR part 573.

To market a food additive, a sponsor must first petition FDA by submitting information that includes all relevant data bearing on the effect the additive is intended to have in or on food and full reports of investigations made with respect to the safety of the food additive. If FDA approves the petition, FDA publishes a regulation prescribing the conditions of use under which the additive may be safely used. The regulations that apply to food additives used in animal foods and that describe the food additive petition process are published in 21 CFR part 571.

9. Approved Color Additives

A color additive, as defined in 201(t)(1) of the FD&C Act, includes a dye, pigment, or other substance made by a process of synthesis or similar artifice, or extracted, isolated, or otherwise derived, with or without intermediate or final change of identity, from a vegetable, animal, mineral, or other source that is capable of imparting color when added or applied to food. The listing of approved human and animal food color additives is found in 21 CFR parts 73 and 74.

A color additive must be shown to be safe and be listed in the Code of Federal Regulations before it may be used to color foods. An interested person may petition FDA for the listing of a color additive, which includes the submission of data demonstrating the color additive is safe and suitable for the proposed use, as described in 21 CFR part 71. The FDA will, upon written request, advise on the adequacy of studies planned to yield these data (21 CFR 70.42(c)).

10. Animal Food Sampling Program

The Agency's Feed Contaminants Program (FCP) is an animal food sampling and inspection program that addresses most animal food contaminants, including pesticides, industrial chemicals, dioxins, heavy metals, mycotoxins, and pathogens. It does not address drug residues and agents that cause BSE and other transmissible spongiform encephalopathies (TSEs), as those contaminants are tested for under other programs. Under the FCP, FDA conducts random surveillance sample collections and inspections as well as followup investigations when an animal food sample is found to contain violative levels of contaminants.

The contaminants addressed by the FCP can be hazardous to livestock health and production, pet health, and to human health through residues in animal-derived human food. Many of the more frequently identified contaminants in animal food are toxic, carcinogenic, mutagenic, teratogenic, or otherwise deleterious to animals, humans, or both.

Animal food facilities are inspected by FDA and State Agencies. Many of the inspections are performed for FDA by states that have entered into a contract to conduct inspections in accordance with the Agency's procedures. Under State partnership and cooperative agreements, States agree to conduct inspections under their own authorities and to share the results with FDA. Inspections of animal food facilities play an important role in ensuring the safety of the nation's animal food supply.

11. Animal Food Safety Guidance to Industry

FDA has issued numerous guidance documents (hereinafter, "guidance" or "guidances") to assist the animal food industry in implementing food safety regulatory requirements under FDA's jurisdiction. The Agency issues guidances, in accordance with its regulations in § 10.115 (21 CFR 10.115) for "good guidance practices," to describe its interpretation of or policy on a regulatory issue. Guidances do not establish legally enforceable rights or responsibilities and do not legally bind the public or FDA (§ 10.115(d)(1)). Accordingly, regulated industry is not required to employ the approaches contained in a guidance and instead may choose to use an alternative approach, provided that the alternative approach complies with the relevant statutes and regulations (§ 10.115(d)(2)). Although guidances do not legally bind FDA, they represent the Agency's current thinking on a particular interpretation of or policy regarding a given regulatory issue (§ 10.115(d)(3)). Under § 10.115(c)(1) and (g), FDA publishes a guidance in draft form for public comment before issuing the guidance in final form, except where prior public participation is not feasible or appropriate, if the guidance: (1) Sets forth initial interpretations of statutory or regulatory requirements, (2) sets forth changes in interpretation or policy that are of more than a minor nature; (3) includes complex scientific issues, or (4) covers highly controversial issues.

FDA generally issues guidance to industry for the purpose of communicating the Agency's policy decisions and interpretations of its regulatory requirements so that regulated industry better understands how to comply with those requirements. In some cases, the Agency issues guidance specifically targeted to assisting industry in complying with a particular food safety regulation. For example, the Agency has issued several guidances to assist industry in complying with the regulatory requirements for BSE (§§ 589.2000 and 589.2001) (Refs. 7, 8, 9, 10, and 11). In other cases, the Agency issued guidance that is more narrowly focused in scope or is not directly targeted to assisting industry in complying with a particular food safety regulation. For example, the Agency has issued guidance that addresses deoxynivalenol (DON), also known as vomitoxin, in grain and grain by-products used for animal food (Ref. 12) and guidance on measures to address the risk for contamination by *Salmonella* spp. in raw meat foods for companion and captive non-companion carnivores and omnivores (Ref. 13).

12. Animal Food Safety Compliance Policy Guides

FDA issues guidance to its staff in the form of a compliance policy guide (CPG). The primary purpose of a CPG is to explain FDA's policy on regulatory issues related to the statutes and regulations that FDA is responsible for implementing. CPGs advise FDA field inspection and compliance personnel as to FDA's standards and procedures to be applied when determining industry compliance with our regulatory requirements. FDA issues CPGs in accordance with its regulation for good guidance practices in § 10.115 and makes the CPGs available to the public, thereby providing regulated industry with additional insight into how the Agency interprets the statutes and regulations it is responsible for implementing for purposes of assessing compliance with the Agency's regulatory requirements. In general, FDA's animal food safety CPGs are relatively focused in scope. For example, the Agency has issued a CPG regarding *Salmonella* contamination in all food for animals (Ref. 14), and a CPG that sets forth the criteria that are to be used by FDA personnel to determine whether to take action on animal foods containing aflatoxins (Ref. 15).

B. The Food and Drug Administration Amendments Act of 2007

On September 27, 2007, the FDAAA (21 U.S.C. 2102) was signed into law (Pub. L. 110–85). Section 1002(a) of Title X (Food Safety) of the FDAAA requires the Secretary of Health and Human Services (HHS), in consultation with relevant stakeholder groups, including the Association of American Feed Control Officials (AAFCO), veterinary medical associations, animal health organizations, and pet food manufacturers, to issue new regulations establishing, among other things, processing standards for pet foods. A public meeting that included representatives for the previously mentioned stakeholders was held May 13, 2008, after publication of a notice in the **Federal Register** on April 21, 2008 (73 FR 21357).

Neither the FDAAA, nor its legislative history, described what Congress meant by ''processing standards'' for pet food. In many instances the same ingredients and manufacturing processes are used to produce animal food for both non-food-producing animals, including pets, and food-producing animals. FDA determined that it would not be feasible to implement or enforce processing standards that only applied to one segment of the industry (i.e., pet food.)

The proposed rule for process control standards that the Agency was developing (see the discussion in section II.A.1) included all animal food. After FDAAA was signed into law, a discussion of FDAAA and the requirements for processing standards for pet food was added to the preamble of the proposed rule for process controls standards to clarify that the proposed rule would satisfy these requirements for pet food. After FSMA was enacted, the Agency decided to issue one rule that would satisfy the mandate of section 1002(a) of FDAAA and section 103 of FSMA.

C. FDA Food Safety Modernization Act

1. Requirements for Food Facilities

FSMA was signed into law by the President on January 4, 2011 (Pub. L. 111–353). Section 103 of FSMA, Hazard Analysis and Risk-Based Preventive Controls, amends the FD&C Act to create a new section 418 (21 U.S.C. 350g) with the same name. Many of the provisions in section 103 of FSMA that are relevant to this rulemaking are codified in section 418 of the FD&C Act.

a. General requirements. Section 418 of the FD&C Act contains requirements applicable to food facilities and mandates Agency rulemaking. Section 418(a) is a general provision that requires the owner, operator, or agent in charge of a facility to evaluate the hazards that could affect food (including animal food) manufactured, processed, packed, or held by the facility, identify and implement preventive controls, monitor the performance of those controls, and maintain records of the monitoring. Section 418(a) specifies that the purpose of the preventive controls is to ''prevent the occurrence of such hazards and provide assurances that such food is not adulterated under section 402 [of the FD&C Act]. . . .''

In addition to those areas specified in section 418(a) of the FD&C Act, sections 418(b) through (i) contain more specific requirements applicable to facilities. These include corrective actions (section 418(e)), verification (section 418(f)), a written plan and documentation (section 418(h)), and reanalysis of hazards (section 418(i)). Section 103(e) of FSMA creates a new section 301(uu) in the FD&C Act (21 U.S.C. 331(uu)) to prohibit ''[t]he operation of a facility that manufactures, processes, packs, or holds food for sale in the United States if the owner, operator, or agent in charge of such facility is not in compliance with section 418 [of the FD&C Act].'' Section X discusses proposed requirements (proposed subpart C) that would implement these provisions of section 418 of the FD&C Act.

b. Qualified facilities. Section 418(l) of the FD&C Act (Modified Requirements for Qualified Facilities) establishes criteria for a facility to be a qualified facility, establishes an exemption for qualified facilities, establishes modified requirements for qualified facilities, and provides that the Secretary may withdraw the exemption otherwise granted to qualified facilities in specified circumstances. Under section 418(l)(1) of the FD&C Act, a facility is a qualified facility if: (1) It is a very small business as the term would be defined by this rulemaking or (2) it falls within specified limitations on the average annual monetary value of its sales and types of customers. Section 418(l)(2)(A) of the FD&C Act exempts a qualified facility from the requirements for hazard analysis and risk-based preventive controls as set forth in sections 418(a) through (i) of the FD&C Act, as well as the requirements issued under section 418(n) of the FD&C Act. Section 418(l)(2)(B) of the FD&C Act requires a qualified facility to submit documentation to the Secretary of HHS (the Secretary) related to its qualified status and also submit either documentation of the facility's implementation and monitoring of preventive controls or documentation of its compliance with other appropriate non-Federal food safety laws. Section 418(l)(3) of the FD&C Act authorizes the Secretary to withdraw the exemption from a qualified facility in specified circumstances. Section VIII.C discusses a proposed exemption for qualified facilities (proposed § 507.5(d)). Section XI discusses a proposed process for withdrawing an exemption for a qualified facility (proposed subpart D). Section VIII.D discusses proposed requirements that apply to qualified facilities (proposed § 507.7).

c. Exemptions and exceptions. In addition to the exemption for qualified facilities in section 418(l)(2)(A) of the FD&C Act, there are several other exemptions and exceptions to the requirements specified in section 418 of the FD&C Act. Section 418(j) of the FD&C Act provides an exemption for facilities that are required to comply and are in compliance with the regulations for seafood HACCP, juice HACCP, or thermally processed low-acid foods packed in hermetically sealed containers. Section 418(k) of the FD&C Act provides an exception for activities of facilities subject to section 419 of the FD&C Act (Standards for Produce Safety). Section 103(g) of FSMA provides an exemption for certain activities regarding a dietary supplement that is in compliance with section 402(g)(2) of the FD&C Act and section 761 of the FD&C Act (21 U.S.C. 379aa–1). For animal food facilities, only two of those exemptions are relevant: activities that are subject to the requirements for thermally processed low-acid foods packed in hermetically sealed containers (proposed § 507.5(b)), and section 419 of the FD&C Act (proposed § 507.5(c)) as discussed in section VIII.C.

2. Requirements for Agency Rulemaking

Section 103 of FSMA contains two separate rulemaking provisions. Section 103(a) of FSMA requires rulemaking related to the hazard analysis and risk-based preventive controls required by section 418 of the FD&C Act. In addition, section 103(c) of FSMA requires rulemaking in two areas: (1) Clarification of certain aspects of the definition of the term ''farm'' under section 415 of the FD&C Act (Registration of Food Facilities) and (2) possible exemption from or modification of requirements of section 418 and section 421 of the FD&C Act (21 U.S.C. 350j) (Targeting of Inspection Resources for Domestic Facilities, Foreign Facilities, and Ports of Entry; Annual Report) for certain facilities as the Secretary deems appropriate and as further specified in section 103(c)(1)(D) of FSMA.

a. General rulemaking requirements. Section 418(n)(1)(A) of the FD&C Act requires that not later than 18 months after the date of FSMA's enactment, the Secretary issue regulations ''to establish science-based minimum standards for conducting a hazard analysis, documenting hazards, implementing preventive controls, and documenting the implementation of the preventive controls. . . .''

b. Definition of small and very small business. Section 418(l)(5) of the FD&C Act requires the Secretary, in consultation with the Secretary of Agriculture, to conduct a study of the food processing sector regulated by the Secretary and to make determinations in five areas. These areas include, in part: (1) Distribution of food production by type and size of operation, (2) the proportion of food produced by each type and size of operation, (3) the number and types of food facilities co-located on farms, (4) the incidence of foodborne illness originating from each size and type of operation, and (5) the effect on foodborne illness risk associated with certain activities regarding food.

Section 418(n)(1)(B) of the FD&C Act requires that the regulations define the terms ''small business'' and ''very small business,'' taking into consideration the study of the food processing sector required by section 418(l)(5) of the FD&C Act. These terms are significant because section 103 of FSMA contains several provisions specific to such entities.

- Small and very small businesses are subject to modifications or exemptions from requirements under section 418 or 421 of the FD&C Act for facilities engaged only in specific types of on-farm activities and involving foods that the Secretary determines to be low risk (section 103(c)(1)(D) of FSMA).
- Small and very small businesses are not subject to section 418 of the FD&C Act until 6 months (small businesses) or 18 months (very small businesses) after the effective date of FDA's final rule (section 103(i) of FSMA).
- A very small business is deemed a ''qualified facility'' and would, therefore, qualify for the exemptions as discussed in section VIII.C.1. (section 418(l)(1)(B) of the FD&C Act).

Consistent with section 418(l)(5) of the FD&C Act, FDA has consulted with the USDA during its study of the food processing sector. The study is available in the docket established for this proposed rule (Ref. 16). The Agency requests comment on that study. Section VIII.B discusses the proposed definitions for small business and very small business for animal food facilities. FDA will consider comments regarding the study, as well as comments regarding the proposed definitions for small and very small business, in any final rule based on this proposed rule.

c. Clarification of the term ''facility.'' Generally, section 418 of the FD&C Act applies to the owner, operator, or agent in charge of a ''facility.'' Section 418(o)(2) of the FD&C Act defines ''facility'' as ''a domestic facility or a foreign facility that is required to register under section 415.'' Section 415 of the FD&C Act, in turn, requires any facility engaged in manufacturing, processing, packing, or holding food for consumption in the United States to register with the Secretary.

The requirement in section 415 of the FD&C Act that a facility must register does not apply to farms. FDA's implementing regulations for section 415 (21 CFR part 1, subpart H; later in this document stated as the section 415 registration regulations) define ''farm,'' in relevant part, as ''a facility in one general physical location devoted to the growing and harvesting of crops, the raising of animals (including seafood), or both'' (§ 1.227(b)(3)) (21 CFR 1.227(b)(3)).

The term ''farm'' includes a facility that packs or holds food, provided that all food used in such activities is grown, raised, or consumed on that farm or another farm under the same ownership (§ 1.227(b)(3)(i)). Under that same definition, the term ''farm'' also includes a facility that manufactures/processes food, provided that all food used in such activities is consumed on that farm or another farm under the same ownership (§ 1.227(b)(3)(ii)).

Section 103(c)(1)(A) of FSMA requires that not later than 9 months after the date of enactment, the Secretary publish a notice of proposed rulemaking in the **Federal Register** to issue regulations for purposes of section 415 of the FD&C Act with respect to ''activities that constitute on-farm packing or holding of food that is not grown, raised, or consumed on such farm or another farm under the same ownership'' and ''activities that constitute on-farm manufacturing or processing of food that is not consumed on that farm or on another farm under common ownership.'' The regulation is intended to ''enhance the implementation'' of section 415 and ''clarify the activities that are included within the definition of the term ''facility'' (section 301(c)(1)(B) of FSMA). In section VIII.E of the document for the proposed rule for preventive controls for human food (78 FR 3646), the Agency discusses the proposal to revise the section 415 registration regulations to enhance the implementation of section 415 and to clarify the definition of the term ''facility.'' That discussion applies to activities related to animal food and animal food facilities as well.

d. Science-based risk analysis and requirements under sections 418 and 421 of the FD&C Act. Section 103(c)(1)(C) of FSMA requires that in issuing the proposed rule the Secretary conduct a science-based risk analysis of:

- "Specific types of on-farm packing or holding of food that is not grown, raised, or consumed on such farm or another farm under the same ownership, as such packing and holding relates to specific foods; and
- Specific on-farm manufacturing and processing activities as such activities relate to specific foods that are not consumed on that farm or on another farm under common ownership."

As part of the rulemaking, the Secretary is required to consider the results of the science-based risk analysis and exempt certain facilities from the requirements in sections 418 and 421 of the FD&C Act or modify those requirements, as the Secretary determines appropriate, if such facilities are only engaged in specific types of on-farm manufacturing, processing, packing, or holding activities the Secretary determines to be low risk, and involving specific foods that the Secretary determines to be low risk (section 103(c)(1)(D)(i) of FSMA). Any exemption or modification is limited to small and very small businesses (section 103(c)(1)(D)(ii) of FSMA).

Section VII discusses the Agency's approach to the requirement in FSMA section 103(c) for a science-based risk analysis of the types of on-farm manufacturing, processing, packing, or holding operations that can involve animal food that is not consumed on that farm or on another farm under common ownership for purposes of section 415 of the FD&C Act and request comment on that approach. The final approach will consider comments received to this proposed rule.

Section VIII.C discusses proposed exemptions for small and very small businesses that are solely engaged in certain types of "low risk" activities involving the on-farm manufacturing, processing, packing, and holding of certain "low risk" animal foods from the requirements of section 418 of the FD&C Act (proposed § 507.5(e) and (f)). The Agency also discusses its tentative conclusion that it should not exempt or modify the frequency requirements under section 421 based solely upon whether a facility only engages in such low-risk activity/food combinations and is a small or very small business.

e. Exemption or modification of requirements for certain facilities. Under section 418(m) of the FD&C Act, the Secretary may exempt or modify the requirements for compliance of section 418 of the FD&C Act for hazard analysis and preventive controls for facilities that are solely engaged in the storage of raw agricultural commodities (RACs) (other than fruits and vegetables) intended for further distribution or processing. As discussed in section VIII.C, in accordance with the discretionary language of section 418(m), FDA tentatively concludes that facilities solely engaged in the storage of RACs for animal food, other than fruits and vegetables, intended for further distribution or processing should be exempt from the requirements for hazard analysis and preventive controls that the Agency is proposing in subpart C of part 507. However, as discussed in section VIII.C, the Agency is asking for comment on whether facilities solely engaged in the storage of grains that are RACs for animal food should be included in the final rule.

Section 418(m) of the FD&C Act also authorizes the Secretary to exempt or modify the requirements for compliance with section 418 for facilities that are solely engaged in the storage of packaged foods that are not exposed to the environment. Section VIII.E describes the proposal for how the requirements of proposed part 507 would apply to such facilities that store animal food (proposed § 507.10). Section X.I discusses the proposed modified requirements for such facilities, directed at the storage of packaged animal foods that are not exposed to the environment and that require time/temperature control to limit the growth of, or toxin formation by, microorganisms of animal and human health significance (proposed § 507.48).

FDA proposes to implement section 103 of FSMA in several regulations, rather than a single regulation that covers all food and hazards subject to preventive controls. This proposal is applicable to certain hazards that may be associated with a food facility that manufactures, processes, packs or holds animal food. Section 103 of FSMA applies to "food," which is not limited to human food. Section 201(f) of the FD&C Act defines "food" to include "articles used for food or drink for man or other animals." FDA tentatively concludes that the differences between human and animal food are best addressed through separate rulemakings. Section 418(m) of the FD&C Act authorizes the Secretary, by regulation, to modify the requirements for compliance under the section with respect to facilities that are engaged solely in the production of food for animals other than man. The Agency has tentatively concluded that the requirements of section 418 of the FD&C Act are needed to ensure the safety of animal food and in turn the health of animals, the health of humans who are exposed to animal food, and the safety of animal derived products for human consumption. Therefore, the Agency is proposing requirements to implement section 418 of the FD&C Act for animal food with only few modifications (e.g., no allergen controls.) The Agency requests comment on whether the requirements in section 418 of the FD&C Act should be modified further for facilities that are solely engaged in the production of food for animals other than man, based on scientific and public health principles.

f. Intentional adulteration. This proposed rulemaking is not intended to address "hazards that may be intentionally introduced, including by acts of terrorism" (section 418(b)(2) of the FD&C Act). FDA plans to address section 103 of FSMA regarding such hazards in a separate rulemaking in the future. FDA tentatively concludes that intentional hazards, which are not addressed in traditional HACCP or other food safety systems, likely will require different kinds of controls and would be best addressed in a separate rulemaking. However, FDA also recognizes that some kinds of intentional adulterants could be viewed as reasonably likely to occur, e.g., in animal foods concerning which there is a widely recognized risk of economically motivated adulteration in certain circumstances. An example of this kind of hazard is the addition of melamine to certain food products apparently to enhance perceived quality and/or protein content. The Agency requests comment on whether to include potential hazards that may be intentionally introduced for economic reasons. The Agency also requests comment on when an economically motivated adulterant can be considered reasonably likely to occur.

D. Preventive Controls and Hazard Analysis and Critical Control Points (HACCP) Systems

HACCP is a preventive strategy for food safety that involves a systematic approach to the identification and assessment of the risk (likelihood of occurrence and severity) of hazards from a particular food or food production process or practice and the control of those hazards. FDA tentatively concludes for several reasons that HACCP is the appropriate framework to reference in interpreting and implementing section 103 of FSMA. For a full discussion of HACCP and preventive controls systems comparisons, please see section II.C of the document for the proposed rule for the preventive controls for human food (78 FR 3646).

E. Animal Food Safety Incidents: Examples and Monitoring

1. Examples of Animal Food Safety Incidents

Historically, the Agency has focused on specific animal food safety issues as problems arise, typically after the distribution of the contaminated animal food. Examples include safety issues related to BSE, chronic wasting disease, mycotoxins (especially aflatoxin in animal food intended for lactating dairy cattle), dioxins, melamine, and microbial contamination in pet foods.

The massive pet food recall due to adulteration of pet food with melamine and cyanuric acid (chemicals called triazines) in 2007 is a prime example. The actions taken by two protein suppliers in China to intentionally adulterate wheat gluten and rice protein concentrate for economic reasons affected a large number of pet food facilities in the United States and created a nationwide problem by causing illness and death in many dogs and cats. The addition of melamine to wheat gluten and rice protein concentrate resulted in a high nitrogen reading during Kjeldahl testing, a test method used to estimate protein levels in foods. By adding the melamine, a non-protein source of nitrogen, the suppliers created a falsely high estimate of protein in their products. While melamine by itself is relatively non-toxic to mammals, the melamine used to adulterate the wheat gluten and rice protein concentrate in this incident had been combined with cyanuric acid, creating a mixture that became toxic. The presence of cyanuric acid with melamine resulted in a precipitation of crystals (melamine cyanurate) when mixed in a solution (Ref. 17). When the animals ingested the adulterated food, the mix of these two chemicals was absorbed into the blood stream and ultimately created an accumulation of crystals in the tubules of the animals' kidneys, leading to kidney disease and death in many animals.

By the time the cause of the illness and deaths was identified, melamine and cyanuric acid contaminated ingredients resulted in the adulteration of millions of individual servings of pet food. Checks to ensure the safety of the imported ingredients had not been conducted by the importer or by the pet food manufacturers that incorporated the ingredients into pet food.

During the investigation, FDA determined that leftovers from the production of pet food (commonly called fines) and salvaged, finished pet food products were routinely used in the production of feed for some food-producing animals (e.g., swine and poultry). It was ultimately discovered that some of these fines and salvaged pet food were adulterated with melamine (and other triazine analogs). Urine from swine (that were being raised for human food consumption) that had eaten this contaminated food was tested and found to contain melamine. This discovery resulted in the holding of animals before their marketing for human food in order to provide time for the U.S. government to conduct a risk assessment to ensure the safety of the meat for human consumption. It was ultimately determined there was no risk to human health from eating meat from these animals due to the small amounts of contaminants in the animal feed eaten.

The contaminated wheat gluten was also used in the manufacture of fish food used in fish hatcheries for food-producing fish. As a result, there was a recall of the affected fish food. These situations with food-producing animals emphasized the link between adulterated animal food (and ingredients) and the potential for adverse effects on human health.

The melamine incident underscored the difficulty in tracing an adulterated ingredient that has been used in a large number of food products. The list of recalled animal foods was constantly updated for multiple weeks after the initial identification of the adulterated ingredients as the distribution of those ingredients was traced. Pet food companies who thought their pet foods were safe because their formulations did not included the use of wheat gluten or rice protein concentrate were surprised to find some of their products were indeed adulterated with the melamine and cyanuric acid. An FDA investigation revealed that a contracted pet food manufacturer was substituting rice protein concentrate for other sources of protein called for in these formulations without contacting the parent company.

Additional incidents of animal food contamination not discovered until after the food was distributed include the detection of dioxin in feed. Dioxin has been linked to adverse health effects in humans, such as cancer, immune suppression, and reproductive or developmental effects. Dioxin is a concern in food-producing animals because human dioxin exposure in the United States comes primarily from the consumption of animal products. In 1997, the USDA's Food Safety and Inspection Service, through their dioxin sampling survey, identified dioxins in poultry tissue. Through a multi-agency investigation, the FDA traced this contamination to high levels of dioxins present in an anti-caking agent (ball clay) used in animal food. That same year, FDA issued a statement to users of ball clay products in animal feed requesting those companies to cease the use of ball clay products in animal feeds and feed ingredients (Ref. 18). In 2002, a foreign government identified high dioxin levels in a mineral product intended for animal food imported from the United States (Ref. 19). The source of the dioxin was related to the high temperature used in the mineral manufacturing process. In 2003, another dioxin incident in minerals was identified as a result of an FDA food sampling assignment. In this case, the mineral premix manufacturer purchased a trace mineral that was a by-product of a metal smelting process (Ref. 20). Internationally, in 1999, animal feed contaminated with dioxin and polychlorinated biphenyls in Belgium resulted in animal and human exposure in Europe. The Belgium government estimated the economic impact of the dioxin crisis cost $493 million, of which $106 million was lost in the swine industry alone. The total cost is much greater when factoring in the impact that occurred to the animal and human food industries in European countries that imported contaminated animal food (livestock feed) or human food from Belgium (Ref. 21). In 2009, a dioxin incident occurred in Ireland involving swine feed that resulted in a global recall of Irish pork. This incident resulted in the Irish government providing € 200 million ($266 million) compensation packages for the Irish pork industry due to their economic losses (Ref. 22). These incidents raised public awareness of the problem of dioxin contamination in animal food.

Another animal food contaminant that can cause illness and injury to animals and humans is aflatoxin. Aflatoxins are naturally occurring mycotoxins that are produced by many species of the fungus *Aspergillus* on certain agricultural commodities. Since their discovery in the early 1960's, aflatoxins have been shown to be toxic to animals and humans. Aflatoxins have also been shown to be carcinogenic to laboratory test animals. After consumption, aflatoxins are metabolized by the liver to a reactive intermediate and eliminated as aflatoxin M1 in milk or as aflatoxicol in urine. High level aflatoxin exposure produces acute damage and cirrhosis of the liver as well as cancer of the liver. It appears that no animal species, including humans, is immune to the acute toxic effects of aflatoxins. In 2005, a pet food company in South

Carolina recalled dog food that was contaminated with aflatoxin (Ref. 23). The Agency received reports from 4 states of illness in over 40 dogs, including 23 deaths, associated with the consumption of the contaminated pet food. In addition, the company's contaminated pet food was exported to at least 29 foreign countries. The source of this contamination was traced to local corn, which had been contaminated with aflatoxin before entering the pet food facility.

Microbial contamination of animal food is also a high concern for the Agency, not only for animals consuming the contaminated food, but also for humans that handle that contaminated animal food. In 2007, FDA identified S. Schwarzengrund, a rare serotype of *Salmonella* associated with human illness, in a pet food. The Center for Disease Control and Prevention (CDC) traced this rare strain of *Salmonella* to a pet food manufacturing facility located in Pennsylvania. Analytical tests conducted by FDA confirmed S. Schwarzengrund at the Pennsylvania facility. A recall was issued for two brands of dry dog food and the manufacturing facility ceased operations for 5 months for cleaning and disinfecting. Despite the facility's efforts, additional S. Schwarzengrund illnesses in humans were reported to CDC. After further investigations by FDA, the pet food manufacturing facility issued a nationwide voluntary recall of all dry dog and cat food products produced at the facility over a 5 month period. This recall involved approximately 23,109 tons of dry pet foods, representing 105 brands. While no pets were reported sick, 79 people in 21 states were reported ill due to the handling of pet food contaminated with this *Salmonella* strain (Ref. 24).

In 2010, the CDC notified FDA of an outbreak of salmonellosis (*Salmonella* infection) in people in the United Kingdom and the United States. News reports from the United Kingdom indicated over 200 people had become ill, all from the same strain of *Salmonella* (Ref. 25). UK officials had determined patients in the United Kingdom had been exposed to frozen rodents used as animal food for reptiles and determined these frozen rodents were contaminated with the same strain of *Salmonella* that was causing the human illness outbreak. U.K. officials traced the origin of these contaminated frozen rodents to a supplier in the United States. UK officials then contacted the CDC. The CDC determined from illness reports that 34 patients in 17 states in the United States were diagnosed with salmonellosis associated with the same strain of *Salmonella* as the patients in the United Kingdom and of that found in the frozen rodents (Ref. 26). FDA inspected the facility producing the frozen rodents and isolated the same strain of *Salmonella* from frozen rodent products sampled at the facility. The facility had distributed frozen rodents as animal food worldwide.

In June of 2008, following an inspection, FDA initiated a mass seizure of animal food at a pet food distribution center after finding the animal food products were vulnerable to contamination, such as microbial contamination, as a result of infestation of the facility by rodents, birds and other pests. Rodent pellets, rodent urine stains, and bird droppings were found throughout the facility, including on bags and pouches of pet food. Rodents had chewed holes in some of the bags of dry dog and cat food and bird seed. The facility was not taking measures to control pest infestation.

Another mass seizure of animal food was executed in August of 2009 at a feed mill because of similar violations. In both cases, the seized products violated section 402(a)(4) of the FD&C Act because the animal food was being held under insanitary conditions whereby it may have become contaminated with filth or rendered injurious to health.

In April 2012, epidemiologic and laboratory investigations conducted by officials in local, state, and federal public health, agriculture, and regulatory agencies linked a *Salmonella* Infantis outbreak to contaminated dry dog food produced by a single production facility located in South Carolina. A total of 49 people (47 individuals in 20 states and 2 individuals in Canada) were reported infected with *Salmonella* Infantis. Among the 24 human patients with available information, 10 were hospitalized. The results from product testing by multiple agencies along with production codes provided by ill persons, led to multiple recalls by several companies with animal food products manufactured at the implicated production facility. The recalls included 17 brands representing over 30,000 tons of dry dog and cat food produced at the facility. This was the second documented outbreak of human salmonellosis linked to dry pet food in the United States (Ref. 27) (Ref. 28).

These examples demonstrate that the safe production and distribution of animal food and ingredients, along with safe meat, milk, and eggs derived from animals that consume this food is an important public health concern, both domestically and globally. The Agency needs to assure the consumer, both here and abroad, that it has a regulatory system designed to ensure production of safe animal food in the United States. Requiring facilities to manufacture, process, pack, or hold animal food under these proposed CGMPs and proposed preventive controls program would help provide that assurance. In addition, the U.S. Government, the animal food industry, animal producers, pet owners and consumers need to have assurance that animal food imported into the United States is safe.

2. Monitoring and Recalls

FDA monitors adverse food events through various means, such as FDA's Reportable Food Registry, FDA's Pet Food Early Warning Surveillance System, consumer complaints, tracking industry recalls and FDA and State inspection findings. From fiscal year (October through September) 2006 through 2012, there were 2,277 animal food product recalls. In 2007 alone, 1,054 animal food products were recalled due to contamination with melamine. Reasons for other animal food recalls include contamination with aflatoxins, dioxins, *Salmonella,* or metal fragments; improper labeling, such as no BSE warning; and subpotent or superpotent nutrient levels, such as elevated levels of vitamin D, copper, zinc, or urea and low levels of potassium, vitamin D, or thiamine. In fiscal year 2012, there were 191 consumer complaints of ill pets reported to FDA related to the dog food contaminated with *Salmonella* Infantis, discussed previously in this section.

For calendar years 2008 through 2012, over 2,500 consumer complaints were called into FDA's district offices regarding animal food for pets and livestock. The complaints ranged from animals refusing to eat their food to animal illness and deaths associated with consumption of an animal food. During the melamine contamination incident in 2007, FDA received over 13,000 consumer complaints about pet food, and over 18,000 calls. Many of these consumer complaints were associated with recalled pet food products contaminated with melamine and cyanuric acid (a contamination that was linked by laboratory testing to illness and deaths in animals as discussed in section II.E.1).

In September of 2009, the Agency established the Reportable Food Registry (RFR), where manufacturers, processors, packers, and holders of human or animal food are required to report to the Agency if there is reasonable probability that an article of human or animal food will cause serious adverse health consequences or death to humans or animals. From September 2009 through September 2012 the Agency received 71 primary animal food RFR reports. A primary report is the initial report concerning a reportable food from either industry or public health officials, such as federal, state or local regulators. The hazards identified in the primary animal food reports consisted of 27 microbial hazards, 5 physical hazards, and 39 chemical hazards. The microbial hazards were almost exclusively *Salmonella* bacteria found in the finished product. The physical hazards included glass, metal or plastic in the finished animal food, some of which reportedly resulted in animal injury or death. The largest number of animal illnesses and deaths reported to FDA through the RFR and attributable to animal food were associated with a subset of chemical hazards, nutrient imbalances. Some examples of nutrient imbalances associated with animal illnesses and deaths include excessive levels of urea in cattle food, excessive levels of copper in sheep food, inadequate levels of thiamine in cat food, inadequate levels of vitamin D in swine food. In addition, toxic levels of medication (new animal drugs) have been found in non-medicated animal food.

In May, 2010, the Agency implemented the Safety Reporting Portal, where consumers can submit complaints regarding adverse events in animals associated with the consumption of pet food products. From May 2010 through September 2012 the Agency received over 2,900 consumer complaints for pet food through the Safety Reporting Portal and all were reviewed and evaluated by FDA.

F. The Role of Testing as a Verification Measure in a Food Safety System

The safety of food is principally ensured by the effective implementation of scientifically valid preventive control measures throughout the food chain (Refs. 29 and 30). Prevention of hazards in animal food is much more effective than trying to differentiate safe from unsafe food using testing. Although testing is rarely considered a control measure, it plays a very important role in ensuring the safety of food. An important purpose of testing is to verify that control measures, including those related to suppliers and those verified through environmental monitoring, are controlling the hazard (Refs. 31 and 32). Testing is used in conjunction with other verification measures in the food safety system, such as audits of suppliers, observations of whether activities are being conducted according to the food safety plan, and reviewing records to determine whether process controls are meeting specified limits for parameters established in the food safety plan. As discussed in the Appendix to this document (see sections I.C, I.E, and I.F of the Appendix), microbial testing may include:

- Testing raw materials and ingredients to verify that suppliers have significantly minimized or prevented hazards reasonably likely to occur in the raw materials and ingredients;
- Testing the environment to verify that sanitation controls have significantly minimized or prevented the potential for environmental pathogens to contaminate animal food; and
- Testing finished product to verify that preventive controls have significantly minimized or prevented hazards reasonably likely to occur in the animal food.

Each type of testing provides information applicable to managing hazards in animal foods, depending on the animal food and process. The Agency discusses the role of testing as a verification measure in a food safety system in section I of the Appendix to this document.

G. The Role of Supplier Approval and Verification Programs in a Food Safety System

An animal food can become contaminated through the use of contaminated raw materials or ingredients as evident by the large recall of pet food because of contamination of wheat gluten with melamine (see discussion in section II.E.1). The development of a supplier approval and verification program is part of a preventive approach. Because many facilities acting as suppliers procure their raw materials and ingredients from other suppliers, there is often a chain of suppliers before a raw material or other ingredient reaches the manufacturer/processor. Using a preventive approach, a facility receiving raw materials or ingredients from a supplier can help ensure that the supplier (or a supplier to the supplier) has implemented preventive controls to significantly minimize or prevent hazards that the receiving facility has identified as reasonably likely to occur in that raw material or other ingredient unless the receiving facility will itself control the identified hazard.

A supplier approval and verification program is a means of ensuring that raw materials and ingredients are procured from those suppliers that can meet facility specifications and have appropriate programs in place, including those related to the safety of the raw materials and ingredients. A supplier approval program can ensure a methodical approach to identifying such suppliers. A supplier verification program is essential to provide initial and ongoing assurance that suppliers are complying with practices to achieve adequate control of hazards in raw materials or ingredients. The Agency discusses supplier approval and verification programs in more detail in section II of the Appendix to this document.

III. Public Meeting and Preliminary Stakeholder Comments

On April 20, 2011, FDA held a public meeting entitled ‘‘FDA Food Safety Modernization Act: Focus on Preventive Controls for Facilities’’ (notice of the meeting published in the **Federal Register** on April 13, 2011; 76 FR 20588). The purpose of the public meeting was to provide interested persons with an opportunity to discuss implementation of the provisions in section 418 of the FD&C Act. A discussion of this meeting can be found in section IV of the document for the proposed rule for preventive controls for human food (78 FR 3646).

IV. Summary of the Scope of the Proposed Rule

This proposed rule would apply to animal facilities required to register with FDA under section 415 of the FD&C Act, unless subject to an exemption. This would include manufacturing, processing, packing, and holding of finished products that are intended to be fed to animals, including livestock, pets, and other captive animals, as well as the manufacturing, processing, packing, and holding of ingredients that may be used in animal foods. Some industry sectors, such as renderers and grain and oilseed processors, have long been considered animal food manufacturers and would be subject to the proposed rule. In addition, industry sectors that are newer, such as biofuel manufacturing (suppliers of distillers grain for animal food), or other entities that may not have been thought of as animal food manufacturers in the past, such as mineral refining and manufacturing, would be subject to the proposed rule to the extent that they are engaged in manufacturing, processing, packing, or holding of animal food.

This proposed rule would not apply to farms. For example, farms manufacturing, processing, packing, and holding food for consumption by their own animals would not be required to register under section 415 of the FD&C Act and therefore would not be required to comply with the proposed rule. However, if the farm operates an animal food manufacturing business (in addition to its traditional farm activities) that requires registration under section 415 of the FD&C Act, that food manufacturing business would likely need to comply with this proposed rule.

In complying with the Hazard Analysis and Risk-Based Preventive Controls section of the proposed rule (subpart C), facilities that manufacture, process, pack, or hold animal food for a single species of animal would focus on hazards most likely to be associated with the ingredients they use, as well as hazards most likely to occur during manufacturing, processing, packing, or holding at the facility, relevant to that species of animal. Facilities that manufacture, process, pack, or hold an ingredient would focus on reducing hazards associated with the ingredient and those species of animal that may consume animal food containing that ingredient. Facilities that manufacture, process, pack, or hold animal food for a range of species or variety of uses would need to consider a more diverse number and type of hazards. In addition to focusing on hazards associated with their incoming ingredients or the types of equipment they use, a feed mill that manufactures food for multiple species would need to be aware of nutritional sensitivities of the animals for which it makes food. For example, a manufacturer that makes food for swine, which can tolerate a relatively large amount of copper in their diet, and food for sheep, which are very sensitive to copper, would need to adopt controls that would ensure that the sheep food it does not contains levels of copper that are unsafe for sheep.

Pet foods usually contain ingredients from the same sources used to make food for livestock and pet foods are sometimes manufactured in the same facilities as food for livestock. For these reasons the Agency has not proposed different rules for these different types of facilities. However, the hazards associated with pet food may be significantly different from the risks associated with food for livestock, and the facility manufacturing, processing, packing, or holding would need to identify and address these hazards. Pet foods usually come into the home, so in addition to being safe for pets to eat, they also would need to be safe for the pet owner to handle. For example, pet foods and treats have been known to carry *Salmonella* (see section II.E). A facility manufacturing pet food would need to address the potential for injury or illness (including death) from the *Salmonella* hazard in not only animals, but in humans handling that pet food (especially the young, old, or immunocompromised.)

V. Highlights of the Proposed Rule

A. Overview

The proposed rule would establish part 507 and contains regulations regarding the manufacturing, processing, packing, or holding of animal food. The proposed rule would establish new provisions for CGMPs for animal food and ingredients, and it would establish new provisions for risk-based preventive controls.

Under the proposed rule, part 507 would be divided into the following subparts:

- Subpart A—General Provisions;
- Subpart B—Current Good Manufacturing Practice;
- Subpart C—Hazard Analysis and Risk-Based Preventive Controls;
- Subpart D—Withdrawal of an Exemption Applicable to a Qualified Facility;
- Subpart E is Reserved; and
- Subpart F—Requirements Applying to Records That Must Be Established and Maintained.

B. Proposed Subpart A—General Provisions

The proposed rule would establish general provisions under subpart A of part 507. These provisions include the applicability and status, definitions, specified exemptions for certain facilities from the requirements of proposed subpart C (hazard analysis and risk-based preventive controls), and specified exemptions for certain establishments from the requirements from subpart B (current good manufacturing practice). The proposed exemptions from subpart C would be consistent with the requirements established by FSMA or the discretion provided by FSMA. The subjects of the specified exemptions relate to:

- Animal food establishments that do not have to register under section 415 of the FD&C Act;
- Activities subject to existing Agency regulations governing microbiological hazards for low acid canned animal foods;
- Activities subject to the Standards for Produce Safety in section 419 of the FD&C Act;
- A "qualified" facility;
- Certain low-risk packing or holding activity/animal food combinations conducted on a farm by a small or very small business;
- Certain low-risk manufacturing/processing activity/animal food combinations conducted on a farm by a small or very small business;
- Facilities that are solely engaged in the storage of RACs (other than fruits and vegetables) intended for further distribution or processing;
- Facilities that are solely engaged in the holding or transportation of RACs; and
- Facilities solely engaged in the storage of packaged animal food that is not exposed to the environment, although the storage of such food that requires time/temperature control to prevent the growth of, or toxin formation by, pathogenic microorganisms would be subject to modified requirements that would be established in proposed subpart C.

Proposed subpart A would also implement certain provisions in sections 418(l) and (m) of the FD&C Act for modified requirements with respect to implementing the modified requirements specified in section 418(l) of the FD&C Act for facilities that satisfy the statutory criteria for a "qualified facility." The Agency proposes to establish requirements that include:

- Submission to FDA of documentation that the facility is a qualified facility; and
- Submission to FDA of documentation demonstrating that the owner, operator, or agent in charge of the facility has identified the potential hazards associated with the food being produced, is implementing preventive controls to address the hazards, and is monitoring the performance of the preventive controls to ensure that such controls are effective; or
- Submission to FDA of documentation that the facility is in compliance with State, local, county, or other applicable non-Federal food safety law, including relevant laws and regulations of foreign countries.

C. Proposed Subpart B—Current Good Manufacturing Practice

Proposed subpart B would establish general baseline good manufacturing practices for facilities manufacturing, processing, packing, and holding animal food. These provisions would include specific requirements for:

- Personnel in animal food facilities such as following good hygiene practices, and protection of food from contamination from personal effects;
- The plant and grounds including proper cleaning, maintenance, and elimination of pests;

- Sanitary operations including maintaining clean and sanitary conditions of food contact surfaces, proper use and storage of toxic cleaning compounds, and exclusion of pests;
- Sanitary facilities and controls such as the plant's water supply, plumbing, and toilet and hand-washing facilities;
- Equipment and utensils including the cleaning and maintenance of such items and protecting animal food from contamination;
- Processes and controls including following adequate sanitation principles, proper labeling of ingredients and finished animal food, ensuring the safety of raw materials, and prevention of contamination of animal food during processing; and
- Warehousing and distribution to protect animal food against contamination and deterioration.

D. Proposed Subpart C—Hazard Analysis and Risk-Based Preventive Controls

1. Written Food Safety Plan

The Agency proposes to require that the owner, operator, or agent in charge of a facility have and implement a written food safety plan that includes as applicable:

- A hazard analysis;
- Preventive controls;
- Monitoring procedures;
- Corrective Action procedures;
- Verification procedures; and
- A recall plan.

2. Written Hazard Analysis

The Agency proposes to require that the written hazard analysis identify and evaluate known or reasonably foreseeable hazards for each type of animal food manufactured, processed, packed, or held at the facility to determine whether there are hazards that are reasonably likely to occur, including biological, chemical, physical, and radiological hazards. The hazard analysis would include an evaluation of the identified hazards to determine whether the hazards are reasonably likely to occur, including an assessment of the severity of the illness or injury if the hazard were to occur.

3. Written Preventive Controls

The Agency proposes to require that the owner, operator, or agent in charge of a facility identify and implement preventive controls (including at critical control points, if any) to provide assurances that hazards that are reasonably likely to occur will be significantly minimized or prevented and that the animal food manufactured, processed, packed, or held by such facility will not be adulterated under section 402 of the FD&C Act. The preventive controls would include, as appropriate:

- Parameters associated with the control of the hazard and the maximum or minimum value, or combination of values, to which any biological, chemical, physical, or radiological parameter must be controlled to significantly minimize or prevent a hazard that is reasonably likely to occur;
- Process controls;
- Sanitation controls;
- A recall plan; and
- Any other necessary controls.

4. Written Recall Plan

The Agency proposes to require that the written recall plan be developed for animal food with hazards that are reasonably likely to occur.

5. Monitoring

The Agency proposes to require the monitoring of the preventive controls to provide assurance that they are consistently performed, including requirements to establish and implement written monitoring procedures and establish and maintain records documenting the implementation of the monitoring procedures.

6. Corrective Actions

The Agency proposes to require that facilities establish and implement written corrective action procedures that would be used if preventive controls are not properly implemented and take corrective actions in the event of an unanticipated problem.

7. Verification

The Agency proposes to require that facilities conduct certain verification activities, including:

- Validation of a subset of the preventive controls;
- Verification that monitoring is being conducted;
- Verification that appropriate decisions about corrective actions are being made; and
- Verification that the preventive controls are consistently implemented and are effectively and significantly minimizing or preventing the hazards that are reasonably likely to occur.

The Agency also proposes to require reanalysis of the food safety plan at least once every 3 years and more often when circumstances warrant.

8. Modified Requirements for a Facility Solely Engaged in the Storage of Packaged Animal Food That is Not Exposed to the Environment

Acting on the discretion provided to FDA by section 418(m) of the FD&C Act, the Agency proposes to require that the owner, operator, or agent in charge of a facility solely engaged in the storage of packaged animal food that is not exposed to the environment conduct certain activities for any such refrigerated packaged animal food that requires time/temperature control to significantly minimize or prevent the growth of, or toxin production by, microorganisms of animal or human health significance, including:

- Establishing and implementing temperature controls;
- Monitoring the temperature controls;
- Taking appropriate corrective actions when there is a problem with temperature controls;
- Verifying that temperature controls are consistently implemented; and
- Establishing and maintaining the following records:
- Records documenting the monitoring of temperature controls;
- Records of corrective actions; and
- Records documenting verification activities.

The Agency requests comments on these proposed requirements.

9. Qualified Individual

The Agency proposes to establish qualification requirements for a "qualified individual," who would be required to do or oversee the preparation of the food safety plan, validation of preventive controls, review records for implementation and effectiveness of preventive controls and the appropriateness of corrective actions, and perform the reanalysis of a food safety plan. A "qualified individual" would be required to successfully complete training with a standardized curriculum or be otherwise qualified through job experience to develop and apply a food safety system. Job experience may qualify an individual to perform these functions if such experience has provided an individual with knowledge at least equivalent to that provided through the standardized curriculum.

10. List of Required Records

The Agency proposes to establish a list of records that would be required under proposed subpart C, including the written food safety plan and records documenting monitoring of preventive controls, corrective actions, verification, and applicable training for the qualified individual.

E. Proposed Subpart D—Withdrawal of an Exemption Applicable to a Qualified Facility

Proposed subpart D would implement the provisions of section 418(l)(3) of the FD&C Act and establish the conditions under which an exemption granted to a "qualified facility" could be withdrawn, and the procedures that would be followed to withdraw such an exemption.

F. Proposed Subpart F—Requirements Applying to Records That Must Be Established and Maintained

Proposed subpart F would establish requirements that would apply to all records that would be required by the various proposed provisions of proposed part 507, including:

- General requirements related to the content and form of records;
- Additional requirements specific to the food safety plan;
- Requirements for record retention;
- Requirements for official review of records by FDA; and
- Public disclosure.

VI. Compliance Dates

Section 103(i)(1) of FSMA, General Rule, provides that "[t]he amendments made by this section shall take effect 18 months after the date of enactment" (i.e., by July 4, 2012). Section 103(i)(2) of FSMA, Flexibility for Small Businesses, provides that "[n]otwithstanding paragraph (1)," the amendments made by this section "shall apply" to a small business and very small business beginning on the dates that are 6 months and 18 months, respectively, "after the effective date" of FDA's final regulation.

FDA is implementing the amendments made by section 103 to the FD&C Act through this rulemaking for animal food (except as they relate to intentional contamination). FDA tentatively concludes that it is appropriate to provide a sufficient time period following publication of the final regulation for facilities to come into compliance. The final regulation will contain provisions that affect which facilities are subject to section 418 and which provisions apply to particular facilities. Without these provisions of the regulation in effect, facilities would be uncertain as to the applicability of certain requirements to them. Further, FDA tentatively concludes that compliance with section 418 will be facilitated greatly by the detail and explanation that will be provided by the final regulation.

Most animal food facilities have not been subject to CGMPs and no animal food facility has been subject to preventive controls as put forth in this proposed rule. However, individual animal food facilities, either individually or through feed industry associations have implemented SOPs that are likely to be sufficient to satisfy some of the proposed requirements. The Agency tentatively concludes that the concepts in the proposed CGMPs will not be new to the animal food industry. Still, the Agency expects that the majority of facilities will need to make substantial changes if the proposed regulations are adopted. FDA recognizes that it can take time to implement a food safety system for animal food that would require among other things, CGMPs, performance of a hazard analysis, development of preventive controls, and monitoring of preventive controls.

FDA is proposing that the final rule would be effective 60 days after publication in the **Federal Register**, with staggered compliance dates (see section VI.) However, the Agency recognizes that animal food businesses of all sizes may need more time to comply with the new requirements. FDA believes that it is reasonable to allow for 1 year after the date of publication of the final rule for businesses other than small and very small businesses to come into compliance with the new requirements established under FSMA. FDA also believes that it is reasonable to allow for 2 years after the date of publication of the final rule for small businesses to come into compliance with the new requirements established under FSMA, and 3 years after the date of publication of the final rule for very small businesses to come into compliance with the new requirements. FDA intends to work closely with the animal food industry, extension and education organizations, and state partners to develop the tools and training programs needed to facilitate implementation of the final rule.

VII. Rulemaking Required by Section 103(c) of FSMA: On-Farm Activities

A. Section 103(c) of FSMA

1. Clarification of the Activities That Are Included As Part of the Definition of the Term "Facility" under Section 415 of the FD&C Act

Section 103(c)(1)(A) of FSMA requires the Secretary to "publish a notice of proposed rulemaking in the **Federal Register** to promulgate regulations with respect to—(i) activities that constitute on-farm packing or holding of food that is not grown, raised, or consumed on such farm or another farm under the same ownership for purposes of section 415 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C 350d), as amended by [FSMA]; and (ii) activities that constitute on-farm manufacturing or processing of food that is not consumed on that farm or on another farm under common ownership for purposes of such section 415." Section 103(c)(1)(B) of FSMA stipulates that such rulemaking "shall enhance the implementation of such section 415 and clarify the activities that are included as part of the definition of the term "facility" under such section." Section 415 of the FD&C Act, in turn, directs the Secretary to require by regulation that any facility engaged in manufacturing, processing, packing, or holding food for consumption in the United States be registered with the Secretary. The registration requirement in section 415 of the FD&C Act does not apply to farms. FDA regulations that implement section 415 and require food facilities to register with FDA are established in part 1 (21 CFR part 1), subpart H (Registration of Food Facilities) (the section 415 registration regulations).

A discussion of the Agency's clarification of the treatment of activities that are included as part of the definition of the term "facility" in section 415 as well as proposed changes to definitions in the section 415 registration regulations can be found in section VIII of the document for the proposed rule for preventive controls for human food (78 FR 3646).

2. Science-Based Risk Analysis Covering Specific Types of On-Farm Packing, Holding, Manufacturing, Processing, Packing and Holding Activities

Section 103(c)(1)(C) of FSMA directs the Secretary to conduct a science-based risk analysis as part of the section 103(c) rulemaking. The science-based risk analysis is to cover "(i) specific types of on-farm packing or holding of food that is not grown, raised, or consumed on such farm or another farm under the same ownership, as such packing and holding relates to specific foods; and (ii) specific on-farm manufacturing and processing activities as such activities relate to specific foods that are not consumed on that farm or on another farm under common ownership." Section VII.B describes a draft Qualitative Risk Assessment (the section 103(c)(1)(C) draft RA) (Ref. 33) the Agency performed to satisfy this requirement.

3. Exemptions and Modified Requirements for Certain Facilities

Section 103(c)(1)(D)(i) of FSMA requires that, as part of the section 103(c) rulemaking, "the Secretary shall consider the results of the science-based risk analysis . . . and shall exempt certain facilities from the requirements in section 418 of the Federal Food, Drug, and Cosmetic Act (as added by [section 103 of FSMA]) including hazard analysis and preventive controls, and the mandatory inspection frequency in section 421 of such Act (as added by section 201 [of FSMA]), or modify the requirements in such sections 418 or 421, as the Secretary determines appropriate, if such facilities are engaged only in specific types of on-farm manufacturing, processing, packing, or holding activities that the Secretary determines to be low risk involving specific foods the Secretary determines to be low risk." Section 103(c)(1)(D)(ii) of FSMA provides that the exemptions or modifications described in section 103(c)(1)(D)(i) "shall not include an exemption from the requirement to register under section 415 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 350d), as amended by [FSMA], if applicable, and shall apply only to small businesses and very small businesses, as defined in the regulation promulgated under section 418(n) of the Federal Food, Drug, and Cosmetic Act." Section VII.C discusses the results of the section 103(c)(1)(C) draft RA. In section VII.D, the Agency sets forth its tentative conclusions regarding combinations of on-farm manufacturing, processing, packing, and holding activities and animal foods determined to be low risk, considering the results of the section 103(c)(1)(C) draft RA. In section VII.E, the Agency discusses a proposed approach to using the results of the section 103(c)(1)(C) draft RA for the purposes of section 421 of the FD&C Act. Section VIII.C. discusses the Agency's proposal to exempt low-risk combinations of activities and animal foods from the requirements of section 418 of the FD&C Act when performed by farm mixed-type facilities that are small or very small businesses as would be defined in proposed § 507.3.

For a complete discussion of FSMA section 103(c) and on-farm activities, please refer to section VIII.B through VIII.D of the document for the proposed rule for preventive controls for human food (78 FR 3646).

B. Qualitative Risk Assessment of On-Farm Activities Outside of the Farm Definition

As discussed in section VII.A, section 103(c)(1)(C) of FSMA directs the Secretary to conduct a science-based risk analysis as part of the section 103(c) rulemaking. The science-based risk analysis is to cover "(i) specific types of on-farm packing or holding of food that is not grown, raised, or consumed on such farm or another farm under the same ownership, as such packing and holding relates to specific foods; and (ii) specific on-farm manufacturing and processing activities as such activities relate to specific foods that are not consumed on that farm or on another farm under common ownership."

As used in section 103(c)(1) of FSMA, the term "risk analysis" is ambiguous. One interpretation is that the common meaning of the term is intended—a simple evaluation of whether activity/animal food combinations are likely to result in the consumer (animals in relation to food for animals) becoming ill. Another interpretation is that the "risk analysis" should be consistent with the formal definition and related terms used by Codex with respect to food safety (Ref. 34):

- Risk is a function of the probability of an adverse health effect and the severity of that effect, consequential to a hazard(s) in food.
- Risk analysis is a process consisting of three components: risk assessment, risk management and risk communication.
- Risk assessment is a scientifically-based process consisting of hazard identification, hazard characterization, exposure assessment, and risk characterization.
- Risk management is the process, distinct from risk assessment, of weighing policy alternatives, in consultation with interested parties, considering risk assessment and other factors relevant for the health protection of consumers and for the promotion of fair trade practices, and, if needed, selecting appropriate prevention and control options.
- Risk communication is the interactive exchange of information and opinions throughout the risk analysis process concerning risk, risk-related factors and risk perceptions, among risk assessors, risk managers, consumers, industry, the academic community and other interested parties, including the explanation of risk assessment findings and the basis of risk management decisions.

Because section 103(c)(1)(C) of FSMA calls for a science-based risk analysis, the Agency is applying the Codex definitions to the extent possible. It is not clear whether the requirement of section 103(c)(1)(C) of FSMA to conduct a science-based risk analysis was intended to encompass all three components of risk analysis. Section 103(c)(1)(D) of FSMA requires the Secretary to consider the results of the science-based risk analysis and exempt certain facilities from the requirements in section 418 of the FD&C Act, including hazard analysis and preventive controls, and the mandatory inspection frequency of section 421, or to modify those requirements for facilities engaged in on-farm manufacturing, processing, packing, or holding activities determined to be low risk involving animal foods determined to be low risk. Thus, section 103(c)(1)(D) of FSMA is focused on ensuring that the Agency's risk management decisions with respect to exempting or modifying requirements applicable to low-risk on-farm activity/animal food combinations under sections 418 and 421 are science-based, as determined by an analysis of the risk of specific types of on-farm activity/animal food combinations required by section 103(c)(1)(C). The Agency therefore tentatively concludes that the analysis required by section 103(c)(1)(C) should be limited to an assessment of the risk of specific types of on-farm activity/animal food combinations for the purposes of making the risk management decisions required by section 103(c)(1)(D). The risk communication component of the risk analysis is accomplished through the discussion of that assessment in this document, the opportunities for public comment (on the risk assessment and on this proposed rule), and the Agency's evaluation of, and response to, comments in a final rule.

Consistent with this approach, the Agency conducted a qualitative risk assessment (Ref. 33) ("section 103(C)(1)(C) draft RA") related to activity/animal food combinations for the purpose of determining which activity/animal food combinations would be considered low risk. The Agency focused on activity/animal food combinations that were identified as being conducted on farms (and, thus, might be conducted by farm mixed-type facilities), but the Agency did not consider activity/animal food combinations that would be solely within the farm definition (such as the growing and harvesting of crops) and, thus, are not relevant to the requirements of section 103 of FSMA. The Agency focused on considering the risk of activity/animal food combinations rather than separately considering the risk of specific animal food categories because doing so better enabled the Agency to focus on whether a specific manufacturing, processing, packing, or holding activity conducted on animal food by a farm mixed-type facility warranted an exemption from, or modified requirements for, the provisions of section 418 of the FD&C Act.

Elsewhere in this issue of the **Federal Register**, FDA is making the section 103(C)(1)(C) draft RA for animal food available for public comment in the docket established for this proposed rule (Ref. 33). The Agency will consider comments regarding the section 103(C)(1)(C) draft RA in preparing a final version of the RA and will announce the availability of the final version of the RA when it is available. The final preventive controls rule for animal food will take into account the final version of the section 103(C)(1)(C) draft RA.

C. Results of the Qualitative Risk Assessment

In this section, the Agency reports the results of the section 103(C)(1)(C) draft RA, arranged in three lists. References to ''farms'' in these lists should be understood to include farm mixed-type facilities. The lists are shaped by the proposed definitions for harvesting, manufacturing/processing, packing, or holding in the section 415 registration regulations (discussed in section VIII.E of the document for the proposed rule for preventive controls for human food (78 FR 3646), the organizing principles (discussed in section VIII.D of the document for the proposed rule for preventive controls for human food) that form the basis for those proposed definitions, and the examples of activity classifications. As discussed in section VIII.E of the document for the proposed rule for preventive controls for human food, the same activity may be classified differently (among the categories of harvesting, manufacturing/processing, packing, or holding) depending on whether the animal food being operated upon is a RAC and whether the RAC was grown or raised on the farm or farm mixed-type facility performing the activity or a farm under the same ownership and whether the animal food is consumed on the farm that produced it or another farm under the same ownership. The Agency requests comment on the lists in sections VII.C.1, VII.C.2, and VII.C.3.

For purposes of this document, grains are the small, hard fruits or seeds of arable crops, or the crops bearing these fruits or seeds, that are grown and processed for use as meal, flour, baked goods, and cereals (including cereal grains, pseudo cereals, pulses, and other plants used in the same fashion) to be used in animal food. Examples of animal food grains include barley, dent- or flint-corn, sorghum, oats, rice, rye, wheat, and buckwheat. Oilseeds are the small, hard fruits or seeds of arable crops that are grown and processed mainly for the oil that is extracted from them. Examples of animal food oilseeds include soybean, cottonseed, and rapeseed. Grains and oilseeds are field-dried before harvest. Post-harvest drying or dehydrating that further reduces the moisture content of harvested grains and oilseeds for the purpose of storage or transportation is considered an activity separate from field drying done before harvest. In the lists that follow, the terms grain and oilseed are used in a general sense while the terms dried grain and dried oilseed are used to designate specifically those harvested grains and oilseeds that have been further dried or dehydrated for the purpose of storage or transportation.

1. List of Low-Risk On-Farm Packing and Holding Activity/Animal Food Combinations When Conducted on Animal Food Not Grown, Raised, or Consumed on That Farm or Another Farm Under the Same Ownership

The section 103(c)(1)(C) draft RA identified the following low-risk packing and holding activity/animal food combinations when conducted on a farm on animal food not grown, raised, or consumed on that farm or another farm under the same ownership:

- Conveying, weighing, sorting, culling, or grading (incidental to storing):
- Grain (e.g., barley, corn, rice, oat, sorghum, triticale, wheat);
- Oilseed (e.g., cottonseed, linseed, rapeseed, soybean, sunflower);
- Grain or oilseed byproducts;
- Forage (e.g., hay or ensiled material); or
- Other plants or plant byproducts (e.g., almond, peanut or soybean hulls, citrus, other fruit including culled fruit, potatoes, or other vegetables including culled vegetables).
- Storing:
- Dried grain;
- Dried oilseed;
- Byproducts of dried grain or dried oilseed;
- Forage; or
- Other plants or plant byproducts.
- Packing:
- Grain;
- Oilseed;
- Grain or oilseed byproducts;
- Forage; or
- Other plants or plant byproducts.
- Mixing (incidental to packing or storing):
- Grain, whole; or
- Forage.

The Agency notes that the same activities performed on a farm's own RACs, or animal food consumed on the farm or another farm under the same ownership, would be within the farm definition and therefore were outside the scope of the section 103(c)(1)(C) draft RA.

2. List of Low-Risk On-Farm Manufacturing/Processing Activity/ Animal Food Combinations When Conducted on the Farm's Own Raw Agricultural Commodities for Distribution Into Commerce

The section 103(c)(1)(C) draft RA identified the following low-risk manufacturing/processing activity/ animal food combinations when conducted on a farm on the farm's own RACs distribution into commerce:

- Cracking, crimping, or flaking:
- Grain (e.g., barley, corn, rice, oat, sorghum, triticale, wheat);
- Oilseed (e.g., cotton seed, linseed, rapeseed, soybean, sunflower) ; or
- Grain or oilseed byproducts.
- Crushing, grinding, milling, pulverizing, or dry rolling:
- Grain;
- Oilseed;
- Grain or oilseed byproducts;
- Forage (e.g., hay or ensiled material); or
- Other plants or plant byproducts (e.g., such as almond, peanut, or soybean hulls, citrus, other fruit including culled fruit, potatoes, or other vegetables including culled vegetables).
- Making silage
- Chopping, or shredding hay.
- Extracting (mechanical) or wet rolling:
- Grain; or
- Oilseed.

3. List of Low-Risk On-Farm Manufacturing/Processing Activity/ Animal Food Combinations When Conducted on Animal Food Other Than the Farm's Own Raw Agricultural Commodities for Distribution Into Commerce

The section 103(c)(1)(C) draft RA identified the following low-risk manufacturing/processing activity/ animal food combinations when conducted on animal food other than the farm's own RACs for distribution into commerce:

- Cracking, crimping, flaking, or shelling:
- Grain (e.g., barley, corn, rice, oat, sorghum, triticale, wheat);

- Oilseed (e.g., cotton seed, linseed, rapeseed, soybean, sunflower) ; or
- Grain or oilseed byproducts.
- Crushing, grinding, milling, pulverizing, or dry rolling:
- Grain;
- Oilseed;
- Grain or oilseed byproducts;
- Forage (e.g., hay or ensiled material); or
- Other plants or plant byproducts (e.g., such as almond, peanut, or soybean hulls, citrus, other fruit including culled fruit, potatoes, or other vegetables including culled vegetables).
- Making silage.
- Chopping or shredding hay.
- Extracting (mechanical) or wet rolling:
- Grain; or
- Oilseed.
- Labeling:
- Grain, whole;
- Oilseed, whole;
- Sifting, separating, or sizing:
- Grain;
- Oilseed;
- Grain or oilseed byproducts; or
- Other plants or plant byproducts.

D. Tentative Conclusions Regarding On-Farm Low-Risk Activity/Animal Food Combinations Under Section 418 of the FD&C Act

Based on the results of the section 103(c)(1)(C) draft RA regarding on-farm low-risk activity/animal food combinations, the Agency is proposing in § 507.5(e) and (f) to exempt farm mixed-type facilities that are small or very small businesses (as defined in proposed § 507.3) from requirements under section 418 of the FD&C Act if the only activities subject to section 418 that the business conducts are low-risk activity/animal food combinations (see the discussion of these proposed exemptions in section VIII.C). The proposed exemptions would not exempt eligible facilities from the requirement to register under section 415 of the FD&C Act.

E. Tentative Conclusions Regarding On-Farm Low-Risk Activity/Animal Food Combinations Under Section 421 of the FD&C Act

The Agency tentatively concludes that it should consider the low-risk on-farm activity/animal food combinations identified in the section 103(c)(1)(C) draft RA as a factor in identifying high-risk facilities that are small and very small businesses and allocating inspection resources under section 421 of the FD&C Act, Targeting of Inspectional Resources for Domestic Facilities. However, at this time, the Agency tentatively concludes that it should not exempt or modify the frequency requirements under section 421 based solely upon whether a facility only engages in such low-risk activity/animal food combinations and is a small or very small business. Current data limitations impact the Agency's ability to accurately identify such facilities, and it must be able to identify such facilities in order to implement an exempted or modified inspection frequency schedule. The Agency requests comment on whether it should establish data submission requirements that would allow the Agency to identify these types of facilities in order to exempt such facilities from the inspection frequencies, or modify the inspection frequencies that apply to such facilities, under section 421 of the FD&C Act. Examples of data elements that the Agency might need in order to identify these facilities include: Identification of a facility as a farm mixed-type facility, annual monetary value of sales, number of employees, animal food category/activity type. The Agency also requests comment on these possible data elements and any other criteria that may be appropriate for the purposes of allocating inspection resources to these facilities.

VIII. Proposed Subpart A—General Provisions

A. Proposed § 507.1—Applicability and Status

FDA is proposing in § 507.1(a) that the criteria and definitions in part 507 apply in determining whether an animal food is adulterated: (1) Within the meaning of section 402(a)(3) of the FD&C Act in that the animal food has been manufactured under such conditions that it is unfit for food; or (2) within the meaning of section 402(a)(4) of the FD&C Act in that the animal food has been prepared, packed, or held under insanitary conditions whereby it may have become contaminated with filth, or whereby it may have been rendered injurious to health. Proposed § 507.1(a) also would establish that the criteria and definitions in part 507 apply in determining whether an animal food is in violation of section 361 of the Public Health Service Act (the PHS Act) (42 U.S.C. 264). The Agency notes that section 418(a) of the FD&C Act provides that facilities subject to that section must "identify and implement preventive controls to . . . provide assurances that . . . food is not adulterated under section 402 [of the FD&C Act]" and that similar references to preventing adulteration under section 402 of the FD&C Act also appear in section 418(c) and (e). The Agency tentatively concludes that the link between the proposed provisions and the potential for adulteration provides a basis for applying the criteria and definitions in proposed part 507 in determining whether, under particular circumstances, an animal food is adulterated under section 402(a)(3) or (a)(4) or in violation of section 361 of the PHS Act.

Section 103(e) of FSMA amends section 301 of the FD&C Act by adding a new section—(uu)—to the list of acts and the causing thereof that are prohibited. Under section 301(uu), the following act, and the causing thereof, is prohibited:"[t]he operation of a facility that manufactures, processes, packs, or holds food for sale in the United States if the owner, operator, or agent in charge of such facility is not in compliance with section 418 [of the FD&C Act]." To clearly communicate that failure to comply with regulations established under section 418 is a prohibited act, proposed § 507.1(b) would establish that the operation of a facility that manufactures, processes, packs, or holds animal food for sale in the United States if the owner, operator, or agent in charge of such facility is required to comply with, and is not in compliance with, section 418 of the FD&C Act or the regulations implementing section 418 [of the FD&C Act] in subparts C, D, or F of proposed part 507, and § 507.7 of proposed part 507, is a prohibited act under section 301(uu) of the FD&C Act.

Proposed § 507.1(c) would establish that animal food covered by specific current good manufacturing practice regulations also is subject to the requirements of those regulations. FDA has established CGMP requirements for thermally processed low-acid foods packaged in hermetically sealed containers (proposed rule, 41 FR 30444, July 23, 1976; final rule, 44 FR 16209, March 16, 1979; currently established in part 113; and 61 FR 37681, July 19, 1996; currently established in § 500.23). Therefore, animal foods that are subject to 21 CFR 500.23 and part 113 are subject to the requirements of § 500.23 and part 113 even though they are foods covered by the current good manufacturing practice requirements of proposed part 507.

Proposed § 507.1(d) would apply to facilities that manufacture, process, pack, or hold animal food and human food. The Agency wanted to address the instances where a facility may handle both animal and human food in some form, to make it clear which proposed rule would apply for that facility manufacturing, processing, packing, or holding these foods. In addition, in some facilities, "waste" from human food production, such as by-products that may not be edible for humans, or lack nutritional value for humans, are used or sold for animal food. Many species of animals have different digestive systems and nutritional requirements than humans, thus allowing for this use. For the human food manufactured, processed, packed, or held, the facility would need to comply with proposed part 117 (proposed rule for preventive controls for human food (78 FR 3646)), subparts B and C as applicable (facilities subject to subpart B may not also be subject to subpart C), and as subject to the exemptions for proposed part 117. For the animal food manufactured, processed, packed, or held, the facility may choose to comply with either proposed part 507 subparts B and C as applicable or proposed part 117 subparts B and C as applicable, so long as the food safety plan also addresses all hazards that are reasonably likely to occur in the animal food, including nutrient imbalances. ''Food'' used in proposed part 117 would be read to include ''animal food'' when the facility is applying proposed part 117 to the animal food. For example, human food waste that is used for animal food would be treated as ''food'' for the purposes of its animal food use and as waste for the purposes of its role in human food production. The Agency tentatively concludes that this will provide facilities the flexibility to streamline their compliance efforts, while also ensuring human and animal food safety.

FDA requests comment on the applicability of the requirements of this proposed rule to FSIS official establishments that manufacture, process, pack, or hold food for animals. And, if applicable, to what extent should the requirements apply to these establishments?

B. Proposed § 507.3—Definitions

1. Definitions That FDA is Proposing

In developing the following proposed definitions, FDA aimed to be consistent with proposed part 117 of the proposed rule for preventive controls for human food (see the document for the proposed rule for preventive controls for human food (78 FR 3646)). The Agency also considered how these currently existing and proposed definitions should be clarified for use in the animal food context.

The Agency is proposing in § 507.3 that the terms defined in section 201 of the FD&C Act would be applicable to such terms when used in this part, unless otherwise specified. Additional terms are listed, defined, and discussed in alphabetical order in this section. These definitions are based on the Agency's experience in regulating human food, animal food, common usage in the animal food industry, and definitions in section 418 of the FD&C Act.

Proposed § 507.3 defines ''adequate'' as that which is needed to accomplish the intended purpose in keeping with good public health practice.

FDA is proposing to define the term ''affiliate'' as it is defined in section 418(l)(4)(A) of the FD&C Act to mean any facility that controls, is controlled by, or is under common control with another facility. This term relates to the determination of whether a facility meets the definition of a qualified facility.

Proposed § 507.3 defines ''animal food'' as food for animals other than man, and includes pet food, feed, and raw materials and ingredients. When used in this part, the phrase ''animal food'' does not refer to food derived from animals that is intended for human consumption.

Proposed § 507.3 defines ''batter'' to mean a semifluid substance, usually composed of flour and other ingredients, into which principal components of food are dipped or with which they are coated, or which may be used directly to form bakery foods.

Proposed § 507.3 defines ''blanching'' to mean, except for tree nuts and peanuts, a prepackaging heat treatment of foodstuffs for a sufficient time and at a sufficient temperature to partially or completely inactivate the naturally occurring enzymes and to effect other physical or biochemical changes in the food.

Proposed § 507.3 defines ''calendar day'' to mean every day shown on the calendar.

Proposed § 507.3 defines ''critical control point (CCP)'' as a point, step, or procedure in a food process at which control can be applied and is essential to prevent or eliminate a food safety hazard or reduce such hazard to an acceptable level.

The Agency is proposing to define the term ''environmental pathogen'' to mean a microorganism that is of animal or human health significance and is capable of surviving and persisting within the manufacturing, processing, packing, or holding environment. *Salmonella* would be an example of an environmental pathogen, particularly in regards to pet food, given that it is a microorganism of animal or human health significance and is capable of surviving and persisting within the manufacturing, processing, packing, and holding. An animal food may be injurious to the health of animals if it is contaminated with a *Salmonella* serotype that is pathogenic to the animal species intended to consume the food. With respect to the risk to humans, pet food and pet treats that are intended to be fed to animals in homes and are contaminated with any *Salmonella* serotype may be injurious to human health, especially where the food is likely to be directly handled by the elderly or individuals with compromised immune systems, or be ingested by children. FDA requests comment on this definition and the types of organisms that should be considered environmental pathogens for animal food, including whether spores of pathogens such as *Clostridium* spp. and *Bacillus anthracis* should be considered environmental pathogens.

FDA is proposing to define the term ''facility'' as it is defined in section 418(o)(2) of the FD&C Act to mean a domestic facility or a foreign facility that is required to register under section 415 of the FD&C Act, in accordance with part 1, subpart H. FDA tentatively concludes that the definition of facility should include a reference to the regulation that implements section 415 of the FD&C Act and proposed to update the definition in § 1.227 in section VIII.E of the document for the proposed rule for preventive controls for human food (78 FR 3646). The regulation implementing section 415 of the FD&C Act provides important details to help firms determine whether they are required to register.

The Agency is proposing to cross-reference the definition of ''farm'' rather than to define it in proposed part 507 because the definition of ''farm,'' under both current § 1.227(b)(3) and proposed § 1.227 (found in section VIII.E of the document for the proposed rule for preventive controls for human food (78 FR 3646)) includes the word ''facility'' with a meaning that is broader than the meaning of ''facility'' in section 418(o)(2) of the FD&C Act. Under part I, subpart H, the term ''facility'' is not limited to entities that are required to register under section 415 of the FD&C Act. The Agency is proposing to cross-reference the definition of ''farm'' to reduce the potential confusion that could result if the Agency used the term ''facility'' to have two different meanings within proposed part 507.

Proposed § 507.3 defines ''food'' to mean food as defined in section 201(f) of the FD&C Act and includes raw materials and ingredients.

Proposed § 507.3 defines ''food-contact surfaces'' as those surfaces that contact food and those surfaces from which drainage, or other transfer, onto the food or onto surfaces that contact the food ordinarily occurs during the normal course of operations. "Food-contact surfaces" includes food-contact surfaces of utensils and equipment. The Agency is proposing this definition to clarify the meaning of the phrase "food-contact surfaces" when used in this proposed part.

The Agency is proposing to define the term "harvesting" as follows: Harvesting applies to farms and farm mixed-type facilities and means activities that are traditionally performed by farms for the purpose of removing raw agricultural commodities from the place they were grown or raised and preparing them for use as food. Harvesting is limited to activities performed on raw agricultural commodities on the farm on which they were grown or raised, or another farm under the same ownership. Harvesting does not include activities that transform a raw agricultural commodity, as defined in section 201(r) of the FD&C Act, into a processed food as defined in section 201(gg) of the FD&C Act. Gathering, washing, trimming of outer leaves of, removing stems and husks from, sifting, filtering, threshing, shelling, and cooling raw agricultural commodities grown on a farm or another farm under the same ownership are examples of harvesting. The Agency is proposing the same definition of "harvesting" here as in proposed § 1.227 (see section VIII.E of the document for the proposed rule for preventive controls for human food (78 FR 3646)).

The Agency is proposing to define "hazard" to mean any biological, chemical, physical, or radiological agent that is reasonably likely to cause illness or injury in animals or humans in the absence of its control. The phrase "in animals or humans" is included in this definition because a biological, chemical, physical, or radiological agent in animal food could cause injury and illness to not only animals, but to humans that handle the animal food, or eat products (such as milk, meat, or eggs) derived from animals that ingested the food. The Agency is proposing to include radiological agents to implement section 418(b)(1)(A) of the FD&C Act, which includes radiological hazards as an example of known or reasonably foreseeable hazards that may be associated with a facility. For further discussion on the definition of "hazard" and its consistency with HACCP, see section X.B of the document for the proposed rule for preventive controls for human food (78 FR 3646).

The Agency is proposing to define the phrase "hazard reasonably likely to occur" to mean a hazard for which a prudent person who manufactures, processes, packs, or holds food would establish controls because experience, illness data, scientific reports, or other information provides a basis to conclude that there is a reasonable possibility that the hazard will occur in the type of food being manufactured, processed, packed, or held in the absence of those controls. For further discussion on the definition of "hazard reasonably likely to occur" and its consistency with HACCP, see section X.B of the document for the proposed rule for preventive controls for human food (78 FR 3646). This concept is used in FDA's HACCP regulations for juice (21 CFR 120.7(a)(2)) and seafood (§ 123.6(a) (21 CFR 123.6(a))), and in the meat and poultry HACCP regulation (9 CFR 417.2(a)(1)).

The Agency is proposing to define the term "holding" to mean storage of food. Holding facilities would include warehouses, cold storage facilities, storage silos, grain elevators, and liquid storage tanks. For farms and farm mixed-type facilities, holding would also include activities traditionally performed by farms for the safe or effective storage of raw agricultural commodities grown or raised on the same farm or another farm under the same ownership, but does not include activities that transform a raw agricultural commodity, as defined in section 201(r) of the FD&C Act, into a processed food as defined in section 201(gg) of the FD&C Act. The Agency is proposing the same definition of "holding" here as in proposed § 1.227 (see section VIII.E of the document for the proposed rule for preventive controls for human (78 FR 3646)).

The Agency is proposing to define the term "lot" to mean the food produced during a period of time indicated by a specific code.

The Agency is proposing to define the term "manufacturing/processing" to mean making food from one or more ingredients, or synthesizing, preparing, treating, modifying or manipulating food, including food crops or ingredients. The proposed definition would also state that examples of manufacturing/processing activities are cutting, peeling, trimming, washing, waxing, eviscerating, rendering, cooking, baking, freezing, cooling, pasteurizing, homogenizing, mixing, formulating, bottling, milling, grinding, extracting juice, distilling, labeling, or packaging. For farms and farm mixed-type facilities, manufacturing/processing would not include activities that are part of harvesting, packing, or holding. The Agency is proposing the same definition of "manufacturing/processing" here as in proposed § 1.227 (see section VIII.E of the document for the proposed rule for preventive controls for human food (78 FR 3646)).

Proposed § 507.3 defines "microorganisms" to mean yeasts, molds, bacteria, viruses, protozoa, and microscopic parasites and includes species having animal or human health significance. The term "undesirable microorganisms" includes those microorganisms that are of animal and human health significance, that subject food to decomposition, that indicate that food is contaminated with filth, or that otherwise may cause food to be adulterated. FDA considers not only yeasts, molds, bacteria and viruses, but also protozoa and microscopic parasites, to be microorganisms of importance in the safe and sanitary production of animal food.

The Agency is proposing to define the term "mixed-type facility" to mean an establishment that engages in both activities that are exempt from registration under section 415 of the FD&C Act and activities that require the establishment to be registered. An example of such a facility would be a "farm mixed-type facility," which is an establishment that grows and harvests crops or raises animals and may conduct other activities within the farm definition, but also conducts activities that require the establishment to be registered. The Agency is proposing to use the same definition as would be established in proposed § 1.227 (see section VIII.E of the document for the proposed rule for preventive controls for human (78 FR 3646)).

The Agency is proposing to define the term "monitor" to mean to conduct a planned sequence of observations or measurements to assess whether a process, point, or procedure is under control and to produce an accurate record for use in verification. For further discussion on the definition of "monitor" and its consistency with HACCP, see section X.B of the document for the proposed rule for preventive controls for human (78 FR 3646)).

The Agency is proposing to define the term "packaging", when used as a verb, to mean placing food into a container that directly contacts the food and that the consumer receives. This definition would match the definition of "packaging" in proposed § 1.227 (see section VIII.E of the document for the proposed rule for preventive controls for human (78 FR 3646)). For purposes of animal food, the use of the term "consumer" refers to the person purchasing the animal food to feed to an animal(s) and the animal(s) consuming the food.

The Agency is proposing to define the term ''packing'' as it is defined in proposed § 1.227 (see section VIII.E of the document for the proposed rule for preventive controls for human food (78 FR 3646) to mean placing food into a container other than packaging the food. For farms and farm mixed-type facilities, packing also includes activities traditionally performed by farms to prepare raw agricultural commodities grown or raised on the same farm or another farm under the same ownership for storage and transport, but does not include activities that transform a raw agricultural commodity, as defined in section 201(r) of the FD&C Act, into a processed food as defined in section 201(gg) of the FD&C Act.

Proposed § 507.3 defines ''pest'' to mean any objectionable animals or insects including, but not limited to, birds, rodents, flies, and larvae. For example, mice would be objectionable animals in the animal food manufacturing, processing, packing or holding environment because they can cause contamination of food and food contact surfaces with pathogens of animal or human health significance.

Proposed § 507.3 defines ''plant'' to mean the building or establishment or parts thereof, used for or in connection with the manufacturing, processing, packing, or holding of food.

The Agency is proposing to define ''preventive controls'' to mean those risk-based, reasonably appropriate procedures, practices, and processes that a person knowledgeable about the safe manufacturing, processing, packing, or holding of food would employ to significantly minimize or prevent the hazards identified under the hazard analysis that are consistent with the current scientific understanding of safe food manufacturing, processing, packing, or holding at the time of the analysis. The proposed definition would incorporate the definition in section 418(o)(3) of the FD&C Act.

Proposed § 507.3 defines ''qualified end-user'' to mean, with respect to an animal food, the consumer of the food (where the term does not include a business); or a restaurant or retail food establishment (as those terms are defined in § 1.227 of this chapter) that:

a. Is located:

○ In the same State as the qualified facility that sold the food to such restaurant establishment; or

○ Not more than 275 miles from such facility; and

b. Is purchasing the food for sale directly to consumers at such restaurant or retail food establishment.

The proposed definition matches the definition in section 418(l)(4)(B) of the FD&C Act. As discussed previously in this section of the document, for purposes of this proposed rule, the term ''consumer'' refers to the purchaser of the animal food to feed to an animal(s), and the animal(s) consuming the food. With respect to animal food, restaurants include pet shelters, kennels and veterinary facilities in which animal food is provided to animals, as provided in § 1.227 of this chapter.

Proposed § 507.3 defines ''qualified facility'' to mean (when including the sales by any subsidiary; affiliate; or subsidiaries or affiliates, collectively, of any entity of which the facility is a subsidiary or affiliate) a facility that is a very small business as defined in this part, or a facility as to which both of the following apply:

- During the 3-year period preceding the applicable calendar year, the average annual monetary value of the animal food manufactured, processed, packed, or held at such facility that is sold directly to qualified end-users (as defined in this part) during such period exceeded the average annual monetary value of the animal food sold by such facility to all other purchasers; and
- The average annual monetary value of the animal food sold during the 3-year period preceding the applicable calendar year was less than $500,000, adjusted for inflation.

This definition is based on the criteria in section 418(l)(1) of the FD&C Act. The Agency is specifying ''animal food'' in this definition as it intends to only include the sale of food for animals and not the sale of human food in determining whether a facility meets the requirements in those cases where a facility sells both. The Agency requests comment on whether food for animals and humans should be aggregated in determining whether a facility that sells both meets the statutory criteria of a qualified facility.

Proposed § 507.3 defines ''qualified individual'' to mean a person who has successfully completed training in the development and application of risk-based preventive controls at least equivalent to that received under a standardized curriculum recognized as adequate by FDA or is otherwise qualified through job experience to develop and apply a food safety system. The Agency is proposing to define the term ''qualified individual'' to have a concise term to use in proposed provisions that would require that an activity be performed by such an individual. The Agency is proposing to establish requirements for a qualified individual in proposed section § 507.50 (see section X.J).

Proposed § 507.3 defines ''quality control operation'' to mean a planned and systematic procedure for taking all actions necessary to prevent food from being adulterated.

Proposed § 507.3 defines ''reasonably foreseeable hazard'' ''to mean a potential biological, chemical, physical, or radiological hazard that may be associated with the facility or the food. This term is used in FSMA and the concept is grounded in the hazard evaluation process in HACCP systems.

Proposed § 507.3 defines ''rework'' to mean clean, unadulterated food that has been removed from processing for reasons other than insanitary conditions or that has been successfully reconditioned by reprocessing and that is suitable for use as animal food.

Proposed § 507.3 defines ''safe moisture level'' as a level of moisture low enough to prevent the growth of undesirable microorganisms in the finished product under the intended conditions of manufacturing, processing, packing, and holding. The safe moisture level for food is related to its water activity (a_w). An a_w will be considered safe for a food if adequate data are available that demonstrate that the food at or below the given a_w will not support the growth of undesirable microorganisms.

Proposed § 507.3 defines ''sanitize'' to mean to adequately treat cleaned food-contact surfaces by a process that is effective in destroying vegetative cells of microorganisms of animal and human health significance, and in substantially reducing numbers of other undesirable microorganisms, but without adversely affecting the product or its safety for animals or humans. For example, an appropriate sanitizing process for a facility that manufactures, processes, packs or holds animal food can be one that does not cause illness to the person implementing it and does not make the food unsafe for the intended animal species, person handling the food or humans consuming human food derived from animals that consume the animal food. It is well established that sanitizers can be inactivated by organic material and, thus, are not effective unless used on clean surfaces (Ref. 35). The Agency recognizes that in certain situations effective cleaning and sanitizing of food-contact surfaces for animal food helps protect the health of animals by controlling the transmission of animal diseases. Effective cleaning and sanitizing of food-contact surfaces for animal food can also protect human health by preventing transmission of human diseases that occur through handling of the contaminated food.

Proposed § 507.3 defines "should," explaining that "should" is used to state recommended or advisory procedures or identify recommended equipment. "Should" denotes non-binding guidance. Consistent with the Agency's good guidance practices regulation (21 CFR 10.115), proposed provisions containing the word "should" are draft guidance at this stage. They do not create or confer any rights for or on any person and do not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statutes and regulations.

The Agency is proposing to define "significantly minimize" to mean to reduce to an acceptable level, including to eliminate. "Significantly minimize" and "preventive control" are terms used in FSMA and are consistent with the definition of "control measure" in the National Advisory Committee on Microbiological Criteria for Foods (NACMCF) HACCP guidelines, the Codex HACCP Annex, and FDA's HACCP regulation for juice. The NACMCF HACCP guidelines define "control measure" as any action or activity that can be used to prevent, eliminate or reduce a significant hazard (Ref. 29). The Codex HACCP Annex defines "control measure" as any action and activity that can be used to prevent or eliminate a food safety hazard or reduce it to an acceptable level (Ref. 36). For further discussion on the definition of "significantly minimize" and its consistency with the term "control measure" as used in HACCP, see section X.B.4 of the document for the proposed rule for preventive controls for human food (78 FR 3646).

The Agency is proposing to define the term "small business" to mean a business employing fewer than 500 persons. See section VIII.B.2 for additional discussion of small business.

The proposed limit of 500 employees would include all employees of the business rather than be limited to the employees at a particular facility. FDA conducted a study as required by section 418(l)(5) of the FD&C Act that was used to help determine this definition. That study is available in the docket established for this proposed rule (Ref. 16). The Agency requests comment on that study, particularly in regards to business size for animal food facilities. The Agency will consider comments regarding the study, as well as comments regarding its proposed definition for small business, in any final rule based on this proposed rule.

The Agency is proposing to define the term "subsidiary," as it is defined in section 418(l)(4)(D) of the FD&C Act, to mean any company that is owned or controlled directly or indirectly by another company.

The Agency is proposing to define the term "validation" to mean that element of verification focused on collecting and evaluating scientific and technical information to determine whether the food safety plan, when properly implemented, will effectively control the identified hazards.

The Agency is proposing to define the term "verification" to mean those activities, other than monitoring, that establish the validity of the food safety plan and that the system is operating according to the plan. For further discussion on the use of the terms "validation" and "verification" in HACCP, see section X.B.4 of the document for the proposed rule for preventive controls for human food (78 FR 3646).

The Agency is proposing to define the term "very small business" to mean, for purposes of this proposed part 507, a business that has less than $500,000 in total annual sales of animal foods, adjusted for inflation (Option 1 of co-proposal). As one co-proposal, the Agency is proposing to define the term "very small business" to mean a business that has less than $1,000,000 in total annual sales of animal foods, adjusted for inflation (Option 2). As another co-proposal, the Agency is proposing to define the term "very small business" to mean a business that has less than $2,500,000 in total annual sales of animal foods, adjusted for inflation (Option 3). See section VIII.B.2 for additional discussion of the definition of very small business.

The Agency is proposing to define the term "water activity (a_w)" to mean a measure of the free moisture in a food and is the quotient of the water vapor pressure of the substance divided by the vapor pressure of pure water at the same temperature.

2. Food Processing Sector Study and the Definitions of "Small Business" and "Very Small Business"

FDA conducted a Food Processing Sector Study as required by section 418(l)(5) of the FD&C Act (Ref. 16). The purpose of that study was to make determinations in five areas as required by section 418(l)(5)(A) of the FD&C Act and to use the results of the study in defining the terms "small business" and "very small business." These areas include, in part: (1) Distribution of food production by type and size of operation, (2) the proportion of food produced by each type and size of operation, (3) the number and types of food facilities co-located on farms, (4) the incidence of foodborne illness originating from each size and type of operation, and (5) the effect on foodborne illness risk associated with certain activities regarding food. The Food Processing Sector Study provides information on the number of establishments and average sales per establishment by industry and size of operation. FDA's proposed definitions are informed by that study. The food processing sector study is available in the docket established for this proposed rule (Ref. 16). The Agency requests comment on that study. The Agency will consider comments regarding the study, as well as comments regarding its proposed definitions "small business" and "very small business," in any final rule based on this proposed rule.

Section 418(l)(5)(B) of the FD&C Act required consideration of harvestable acres, income, the number of employees, and the volume of product in defining the terms "small business" and "very small business." The Food Processing Sector Study (Ref. 16) concluded that there was no consistent pattern across food categories, including the pet food and animal feed categories, in terms of which sizes of establishments contribute most to foodborne illness risk. "Harvestable acres," "income," "the number of employees," and "the volume of food harvested" are all ways to measure the size of an operation. Income does not appear to be the most relevant measure, since facility income may be derived from multiple sources, many of which are not food-related. "Harvestable acres" and "volume of food harvested" are similar measures that appear primarily relevant to the growing and harvesting of crops, which are activities not subject to this regulation. Harvestable acres and volume of food harvested do not provide a meaningful measure with respect to the risk from pet food or animal feed produced by a farm mixed-type facility (a pet food or animal feed facility co-located on a farm subject to this regulation); the Agency's qualitative risk assessment of manufacturing, processing, packing, and holding activities conducted in a facility co-located on a farm showed that risk was related to activity/animal food combinations; these animal foods could be harvested from large or small farms (see section VII.B for a discussion of that qualitative risk assessment). A high risk activity/animal food combination (i.e., a not low-risk activity/food combination) could be conducted on a farm with many harvestable acres or very few harvestable acres. For example, an on-farm facility mixing and/or blending for the purpose of making a complete animal food (which would not be considered a low-risk activity/food combination) could be one that has very few acres, or the mixing and/or blending for the purpose of making a complete animal food could be a small component of a large farm operation. FDA has previously used both number of employees and annual sales as criteria for defining small and very small businesses, e.g., in § 120.1(b)(1) and (b)(2) (21 CFR 120.1(b)(1) and (b)(2)) for human food. However, FDA has not previously defined small or very small businesses with regard to pet food or animal feed businesses. The Agency has limited data on number of employees, income, and annual sales upon which to base its definitions of small and very small business for animal food, but no data for ‘‘harvestable acres’’ or ‘‘the volume of food harvested.’’

a. Definition of ‘‘Small Business.’’ FDA is proposing to define the term ‘‘small business’’ to mean, for the purposes of part 507, a business employing fewer than 500 persons. The proposed limit of 500 employees would include all employees of the business rather than be limited to the employees at a particular facility. The Agency is proposing to establish the same definition for small business as that which has been established by the U.S. Small Business Administration under 13 CFR part 121 for most food manufacturers. This is also the same definition for small business the Agency used to define a small business in its juice HACCP regulation (§ 120.1(b)(1)). The definition of small business is relevant to two provisions in the proposed rule. It would affect which facilities qualify for the exemption in proposed § 507.5(e) for on-farm packing or holding, and the exemption in proposed § 507.5(f) for on-farm manufacturing/processing, of animal food by a small business if the only activities subject to section 418 of the FD&C Act are the specific low-risk activity/animal food combinations listed in those sections. It would also affect what the compliance date is for facilities that meet the definition.

Effect on Proposed § 507.5(e) and (f)

Under proposed § 507.5(e) a farm mixed-type facility that meets the definition of a small business and only conducts specific packing or holding activity/animal food combinations would be eligible for an exemption from subpart C. Similarly, under proposed § 507.5(f) a farm mixed-type facility that meets the definition of a small business and only conducts specific manufacturing/processing activity/animal food combinations would be eligible for an exemption from subpart C. Based on the Food Processing Sector Study, the Agency estimates that approximately 4,439 facilities would be part of a small business under the proposed definition and thus satisfy the size requirement of the exemption in proposed § 507.5(e) and proposed § 507.5(f). Of those facilities, the Agency estimates that approximately 188 would be co-located on farms. A subset of those facilities would qualify for the exemption from subpart C based on their manufacturing/processing and packing and holding activities.

Other Effects

Based on the Food Processing Sector Study the Agency estimates that businesses employing fewer than 500 employees produce approximately 18 percent (based on sales) of all manufactured food produced in the United States and 86.9 percent of all manufactured pet food and animal feed. As discussed in section VI, the compliance date for a small business would be 2 years after the date of publication of the final rule. Under this proposed definition, 4,439 facilities would be subject to this compliance date.

b. Definition of ‘‘Very Small Business.’’ In addition to defining ‘‘small business,’’ FDA is required to define ‘‘very small business.’’ FDA has not reached a tentative conclusion on how best to define ‘‘very small business’’ for the purposes of this rule. Consequently, the Agency is proposing three possible definitions based on annual sales of animal food of $500,000, $1,000,000, or $2,500,000 and requesting comment on which of these three options to include in a final rule. The Food Processing Sector Study provided information for the development of the three proposed definitions (Ref. 16). The Agency requests comment on whether a dollar amount of sales that is more than, or less than, the $500,000, $1,000,000, or $2,500,000 dollar amounts it is proposing would be appropriate. The Agency also requests comment on how a particular dollar amount of sales would be in keeping with Congressional intent, i.e., in light of the provisions in section 418(l) of the FD&C Act regarding qualified facilities, including the statutory limitations on sales to qualified end-users.

The definition of very small business is relevant to 3 provisions of the proposed rule. It would affect which facilities qualify for the exemption in § 507.5(e) for on-farm packing or holding, and the exemption in § 507.5(f) for on-farm manufacturing/processing, of animal food by a very small business if the only activities subject to section 418 of the FD&C Act are the specific low-risk activity/animal food combinations listed in those sections. It would also affect which facilities are automatically ‘‘qualified’’ facilities subject to the modified requirements in § 507.7 and what the compliance date is for such facilities.

Effect on Proposed § 507.5(e) and (f)

The definition of very small business affects which facilities qualify for the exemption in § 507.5(e) for on-farm packing or holding, and the exemption in § 507.5(f) for on-farm manufacturing/processing, of animal food by a very small business if the only activities subject to section 418 of the FD&C Act are the specific low-risk activity/animal food combinations listed in those sections,

Other Effects

The definition of very small business affects which facilities are automatically ‘‘qualified’’ facilities subject to the modified requirements in proposed § 507.7, and the applicable compliance dates for such facilities. There are two ways a facility may be ‘‘qualified’’ and thus subject to the modified requirements in proposed § 507.7. The first, limited annual monetary value of sales, is based on fixed criteria set out in FSMA section 418(l)(1)(C). The second, as provided by section 418(l)(1)(B), is to be a very small business as defined by FDA. Therefore, the Agency discusses the effect of the proposed definitions for very small business in relation to the existing requirements for qualified facilities in section 418(l)(1)(C).

Less Than $500,000 in Total Annual Sales—Effect on Proposed § 507.5(e) and (f)

One possible definition of the term ‘‘very small business,’’ for the purposes of proposed part 507, would be a business that has less than $500,000 in total annual sales of animal food, adjusted for inflation (Option 1 of the co-proposal). From the Food Processing Sector Study it is apparent that the number of co-located facilities is concentrated at the smaller end of the size spectrum. Using data from Dun & Bradstreet, FDA estimates that 3 co-located facilities would meet the size requirement for the exemptions in proposed § 507.5(e) and (f). A subset of those facilities might then qualify for the exemption from subpart C based on their manufacturing/processing, packing, or holding activities.

Less Than $500,000 in Total Annual Sales—Effect on Number of Qualified Facilities

The proposed definition of $500,000 uses a dollar amount for sales that is, essentially, the same as the maximum dollar amount of sales by a qualified facility to end-users other than those that would satisfy the definition of "qualified end-users," except unlike with section 418(l)(1)(C) of the FD&C Act, there would be no requirement that more than half of sales must be to qualified end-users. The $500,000 definition of very small business would add approximately 3 domestic facilities to the number of qualified facilities. FDA estimates that no additional domestic animal food facilities beyond these 3 domestic facilities would be qualified facilities under section 418(l)(1)(C) of the FD&C Act, leading to a total of 3 domestic qualified facilities. These 3 domestic qualified facilities would have a 3 year compliance date. As a group, businesses with less than $500,000 in total annual sales of animal food produce less than 0.003 percent of all animal food produced in the United States when measured by dollar value.

Less Than $1,000,000 in Total Annual Sales—Effect on Proposed § 507.5(e) and (f)

One possible definition of the term "very small business," for the purposes of proposed part 507, would be a business that has less than $1,000,000 in total annual sales of animal food, adjusted for inflation (Option 2 of the co-proposal). Using data from Dun & Bradstreet (in the Food Processing Sector Study), FDA estimates that the same 3 facilities that met the $500,000 exemption would meet this exemption level but no additional facilities would meet the size requirement for the exemptions in proposed § 507.5(e) and proposed § 507.5(f). A subset of those facilities might then qualify for the exemption from subpart C based on their manufacturing/processing, packing, or holding activities.

Less Than $1,000,000 in Total Annual Sales—Effect on Number of Qualified Facilities

Defining very small business to mean a business that has less than $1,000,000 in total annual sales of animal food would add approximately 619 domestic facilities to the number of qualified facilities. FDA estimates that no additional domestic pet food or animal feed facilities beyond these 619 domestic facilities would be qualified facilities under section 418(l)(1)(C) of the FD&C Act, leading to a total of 619 domestic qualified facilities. These 619 domestic qualified facilities would have a 3-year compliance date. As a group, businesses with less than $1,000,000 in total annual sales of animal food produce less than 1.71 percent of all pet food and animal feed produced in the United States when measured by dollar value.

Less Than $2,500,000 in Total Annual Sales—Effect on Proposed § 507.5(e) and (f)

One possible definition of the term "very small business," for the purposes of proposed part 507, would be a business that has less than $2,500,000 in total annual sales of animal food, adjusted for inflation (Option 3 of the co-proposal). Using data from Dun & Bradstreet, FDA estimates that the same 3 facilities that met the $500,000 and $1,000,000 exemption would met this exemption level but no additional facilities would meet the size requirement for the exemption in proposed § 507.5(e) and proposed § 507.5(f). A subset of those facilities might then qualify for the exemption from subpart C based on their manufacturing/processing, packing, or holding activities.

Less Than $2,500,000 in Total Annual Sales—Effect on Number of Qualified Facilities

As compared to Option 2, defining very small business to mean a business that has less than $2,500,000 in total annual sales of animal food would add another approximately 2,880 domestic facilities to the number of qualified facilities. FDA estimates that no additional domestic pet food or animal feed facilities beyond these 3,499 (the 619 facilities that qualify at the $1,000,000 exemption level plus the 2,880 facilities that qualify at the $2,500,000 exemption level) domestic facilities would be qualified facilities under section 418(l)(1)(C) of the FD&C Act, leading to a total of 3,499 domestic qualified facilities. These 3,499 domestic qualified facilities would have 3 year compliance date. As a group, businesses with less than $2,500,000 in total annual sales of animal food produce less than 20.8 percent of all pet food and animal feed produced in the United States when measured by dollar value.

Differences From the Proposed Preventive Control Rule for Human Food

FDA is proposing different annual gross sales levels for the three definition options of very small business for animal food facilities than proposed for human food facilities. In the proposed rule for preventive controls for human food (78 FR 3646), FDA proposed three options for annual gross sales levels for very small business. Option 1 would be $250,000, Option 2 would be $500,000, and Option 3 would be $1 million. For the proposed rule for preventive controls for animal food, FDA is proposing three different options for annual gross sales levels for very small business. Option 1 would be $500,000, Option 2 would be $1 million, and Option 3 would be $2.5 million. In general, the animal food industry sector is more heavily weighted toward the medium and larger facilities, when based on gross annual sales, than is the human food industry sector. For example, facilities producing livestock or poultry feed often buy and sell product measured in tons, resulting in high annual gross sales. Though the annual gross sales levels would be higher for each option in the proposed animal food rule, the percent of facilities and percent of sales exempted would be comparable to the annual gross sales levels for the three options for the proposed rule for human food.

C. Proposed § 507.5—Exemptions

1. Proposed § 507.5(a)—Exemption Applicable to Establishments Not Required To Register Under Section 415 of the FD&C Act

Proposed § 507.5(a) would exempt establishments not required to register under section 415 of the FD&C Act. According to section 415(c)(1) of the FD&C Act, establishments that are not required to register include farms; restaurants; other retail food establishments; nonprofit food establishments in which food is prepared for or served directly to the consumer; or fishing vessels (except such vessels engaged in processing as defined in 21 CFR 123.3(k)). The Agency has interpreted these terms in § 1.227. For example, in the animal food context, a "restaurant" includes pet shelters, kennels, and veterinary facilities in which food is provided to animals. A "retail food establishment" is an establishment that sells food directly to consumers as their primary business function, where the term "consumer" does not include a business. A grocery store, including the pet food aisle, would be an example. In addition, the Agency has interpreted ''nonprofit food establishment'' to include a charitable entity that provides food or meals for consumption by animals in the United States. To be considered a nonprofit food establishment, the establishment must meet the terms of section 501(c)(3) of the U.S. Internal Revenue Code. Certain nonprofit wildlife rehabilitation centers would likely fall into this category.

In section VIII.B of the document for the proposed rule for preventive controls for human food (78 FR 3646), FDA proposed to further clarify the scope of the definition of ''farm'' for the purposes of section 415 of the FD&C Act to mean a facility in one general physical location devoted to the growing and harvesting of crops, the raising of animals (including seafood), or both. The term ''farm'' would include: (1) Facilities that pack or hold food, provided that all food used in such activities is grown, raised, or consumed on that farm or another farm under the same ownership and (2) facilities that manufacture/process food, provided that all food used in such activities is consumed on that farm or another farm under the same ownership. Because this definition of ''farm'' reflects the Agency's interpretation of the term in section 415 of the FD&C Act, establishments that meet this definition would not be required to register under section 415 of the FD&C Act and would therefore be excluded from the scope of this rulemaking under proposed § 507.5(a). For example, a farm that manufactures/processes food, e.g., by using mobile equipment to mix grain and forage with a commercially produced protein/mineral supplement into a total-mixed ration to feed to dairy cattle on its farm, or another farm under the same ownership, would be exempt from this proposed rule. As another example, a crop farm that grows, harvests, and stores agronomic crops such as alfalfa hay, corn, and other feed grains for distribution into commerce as animal food would be exempt from the proposed rule.

Similarly, the exemption in § 507.5(a) would exempt activities of farm mixed-type facilities that fall within the farm definition previously mentioned. As discussed in section VIII.B of this document and section VIII.E.1 of the document for the proposed rule for preventive controls for human food (78 FR 3646), a ''mixed-type facility'' would be an establishment that engages in both activities that are exempt from registration under section 415 of the FD&C Act and activities that require the establishment to be registered. An example of such a facility would be a ''farm mixed-type facility,'' an establishment that grows and harvests crops or raises animals and may conduct other activities within the farm definition, but also conducts activities that require the establishment to be registered. FDA tentatively concludes that the portion of a farm mixed-type facility that is within the farm definition—and therefore the portion that is exempt from registration under section 415 of the FD&C Act—should be treated the same way for the purposes of proposed § 507.5(a) as the same activities on farms that only conduct activities within the farm definition.

Section 418 of the FD&C Act sets forth requirements for the owner, operator, or agent is in charge of a ''facility,'' defined in 418(o)(2) as a domestic facility or foreign facility that is required to register under section 415. Therefore section 418 of the FD&C Act only applies to establishments that are required to register under section 415.

The Agency tentatively concludes that these facilities should not be subject to the CGMPs in proposed part 507 for several reasons. Establishments that are not required to register under section 415 of the FD&C Act are not commonly known to be sources of animal food adulteration, they do not commonly stockpile large inventories of animal food, and the rapid turnover of inventory further reduces the risk that these establishments will adulterate animal food products they use. In addition, most of the animals that are housed and cared for by this sector are not food-producing animals, narrowing the scope of the human health risk.

Most of these establishments are already regulated by other agencies, often multiple agencies, who already address animal food safety to some degree. For example, many establishments that are not required to register under section 415 of the FD&C Act fall under the purview of the Animal Welfare Act (AWA), implemented by USDA. The AWA and its implementing regulations provide for safe food and housing for animals in indoor, outdoor and sheltered housing establishments, and those under the control of dealers and exhibitors, among others. Implementing regulations enforced by USDA specify that the food provided to animals in these establishments must be uncontaminated and wholesome (e.g., 9 CFR 3.9). In addition, veterinary clinics, among others of these types of establishments, are regulated by State governments.

FDA also has other established regulations that incorporate feeding practices and animal food storage. For example, § 589.2000, Animal Proteins Prohibited in Animal Feed, addresses, among other things, the feeding of ruminant animals. The Agency does inspect ruminant feeders, including farms and other establishments that may feed ruminant animals to ensure compliance with this regulation. Although the focus of the Agency's inspection work under this regulation is farms raising ruminant animals such as cattle, sheep, goats, elk, and bison intended to produce meat and milk for human consumption, the Agency also visits a small number of other establishments to make sure those industry sectors are aware of, and following, these regulations as they care for their ruminant animals.

Certain establishments that are not required to register under section 415 of the FD&C Act conduct nonclinical laboratory studies in animals to support applications for research or marketing permits for products regulated by FDA, including food and color additives, animal food additives, human and animal drugs, medical devices for human use, biological products, and electronic products. These establishments must comply with Good Laboratory Practice regulations already in place in part 58 (21 CFR part 58), which include certain food safety measures. For example, § 58.45 states ''there shall be storage areas, as needed, for feed, bedding, supplies, and equipment. Storage areas for feed and bedding shall be separated from areas housing the test systems and shall be protected against infestation or contamination. Perishable supplies shall be preserved by appropriate means.'' In addition, § 58.90(g) states ''feed and water used for the animals shall be analyzed periodically to ensure that contaminants known to be capable of interfering with the study and reasonably expected to be present in such feed or water are not present at levels above those specified in the protocol . . .''

Finally, while establishments that are not required to register under section 415 of the FD&C Act would not need to comply with the proposed rule, they would still be subject to the adulteration provisions of section 402 of the FD&C Act.

2. Proposed § 507.5(b)—Exemption Applicable to Animal Food Subject to § 500.23 and Part 113-Thermally Processed Low-Acid Foods Packaged in Hermetically Sealed Containers

Section 418(j)(1)(C) of the FD&C Act provides that section 418 of the FD&C Act shall not apply to a facility if the owner, operator, or agent in charge of such facility is required to comply with, and is in compliance with, ''[t]he Thermally Processed Low-Acid Foods Packaged in Hermetically Sealed Containers standards of the [FDA] (or any successor standards).'' (The Agency interprets ''Thermally Processed Low-Acid Foods Packaged in Hermetically Sealed Containers standards'' to mean the requirements of § 500.23 and part 113. Section 500.23 establishes that part 113 also applies to food for animals.) Importantly, section 418(j)(2) of the FD&C Act limits the express exemption associated with § 500.23 and part 113 to microbiological hazards that are regulated under § 500.23 and part 113 (or any successor regulations). FDA considers the language of section 418(j)(1)(C) of the FD&C Act to be ambiguous with regard to application of the exemption. The language of section 418(j)(1)(C) exempts a facility from section 418 of the FD&C Act if the owner, operator, or agent in charge of the facility is required to comply with, and is in compliance with, § 500.23 and part 113 ''with respect to such facility[.]'' However, § 500.23 and part 113 do not apply to ''facilities,'' establishments, or plants. Rather, they apply to the specified foods (low-acid canned foods) and to persons defined as ''commercial processors'' who conduct certain activities involving those foods. See, e.g., § 113.3(d) (definition of ''Commercial processor''), and section 404 of the FD&C Act (21 U.S.C. 344), which provides FDA with legal authority to issue § 500.23 and part 113 (''[The Secretary] shall promulgate regulations providing for the issuance, to manufacturers, processors, or packers of such class of food [presenting specific risks defined in the section] in such locality of permits to which shall be attached such conditions governing the manufacture, processing, or packaging of such class of food . . .''). Thus, it is unclear for purposes of section 418(j)(1)(C) under what circumstances a low-acid canned food processor is required to comply with § 500.23 and part 113 ''with respect to [a] facility,'' especially when such a person also conducts activities involving other foods not subject to § 500.23 and part 113 at the same facility.

The Agency tentatively concludes that it should interpret section 418(j)(1)(C) to exempt those activities of a facility that are subject to § 500.23 and part 113, and only those activities. Such an interpretation would fulfill the apparent goal of the exemption without being too narrow or too broad. The Agency also tentatively concludes that it should include the exemption provided in section 418(j)(1)(C) of the FD&C Act in the proposed rule to establish by regulation the reach of the exemption as the Agency has interpreted it. Proposed § 507.5(b) would provide that subpart C would not apply with respect to activities that are subject to § 500.23 and part 113 (Thermally Processed Low-Acid Foods Packaged in Hermetically Sealed Containers) at a facility if the owner, operator, or agent in charge of the facility is required to comply with, and is in compliance with, § 500.23 and part 113 with respect to such activities. Consistent with section 418(j)(2) of the FD&C Act, proposed § 507.5(b) would establish that the exemption would be applicable only with respect to the microbiological hazards that are regulated under § 500.23 and part 113. A facility that is required to comply with, and is in compliance with, § 500.23 and part 113 would be subject to the requirements in proposed subpart C for hazards such as chemical hazards (e.g., pesticide residues), physical hazards (e.g., metal fragments that could be introduced from equipment) and radiological hazards (e.g., high concentrations of radium-226, radium-228 or uranium in well water used in product). A facility that is required to comply with, and is in compliance with, § 500.23 and part 113 also would be subject to the requirements in proposed subpart C for biological hazards not regulated under § 500.23 and part 113. For example, the heat-stable toxin produced by the *Staphylococcus aureus* is a biological hazard that would not be inactivated or destroyed by the processing required under § 500.23 and part 113 (Ref. 37) (Ref. 38).

The Agency requests comment on the criteria that should be used to determine whether a facility is in compliance with § 500.23 and part 113.

3. Proposed § 507.5(c)—Exemptions Applicable to Activities Subject to Standards for Produce Safety in Section 419 of the FD&C Act

Section 418(k) of the FD&C Act provides that section 418 of the FD&C Act ''shall not apply to activities of a facility that are subject to section 419 [of the FD&C Act].'' Section 419, ''Standards for Produce Safety,'' requires FDA to establish by regulation ''science-based minimum standards for the safe production and harvesting of those types of fruits and vegetables, including specific mixes or categories of fruits and vegetables, that are raw agricultural commodities for which [FDA] has determined that such standards minimize the risk of serious adverse health consequences or death.'' Section 419(h) of the FD&C Act provides that section 419 of the FD&C Act ''shall not apply to activities of a facility that are subject to section 418 [of the FD&C Act.]'' FDA issued a proposed rule to implement section 419 on January 16, 2013 (78 FR 3504.) That proposed rule would apply section 419 to ''farms'' (as would be defined in proposed §§ 1.227 and 1.328 of the proposed rule for preventive controls for human food (78 FR 3646) that are not required to register under section 415 of the FD&C Act and to farms that conduct an activity (or activities) that triggers the section 415 registration requirement (''farm mixed-type facilities''), but only with respect to their activities that are within the farm definition and therefore do not trigger the registration requirement. The Agency tentatively concludes that it should include a provision implementing section 418(k) of the FD&C Act in the proposed rule for clarity and consistency, though section 419 of the FD&C Act applies only to human food. Proposed § 507.5(c) would provide that subpart C would not apply to activities of a facility that are subject to section 419 of the FD&C Act (Standards for Produce Safety).

4. Proposed § 507.5(d)—Exemption Applicable to a Qualified Facility

Section 418(l) of the FD&C Act establishes modified requirements for ''qualified facilities.'' The Agency describes what a qualified facility is in section VIII.D, where the Agency proposes the requirements for such a facility (proposed § 507.7). The Agency also defines the term ''qualified facility'' in proposed § 507.3 (see the discussion of definitions in section VIII.B). Section 418(l)(2)(A) of the FD&C Act provides that a qualified facility ''shall not be subject to the requirements under [sections 418(a) through (i) and (n) of the FD&C Act];'' as a practical matter with respect to the provisions of this proposed rule, section 418(l)(2)(A) of the FD&C Act provides that a qualified facility would be exempt from the requirements of proposed subpart C. Importantly, section 418(l)(3) of the FD&C Act provides that the Secretary of HHS may withdraw the exemption provided in section 418(l)(2)(A) under certain circumstances. The Agency discusses the withdrawal provisions of section 418(l)(3), and its proposed provisions to implement section 418(l)(3) (proposed subpart D), in section XI.

The Agency tentatively concludes that it should include the exemption provided in section 418(l)(2)(A) of the FD&C Act in the proposed rule to establish by regulation the reach of the provision. Proposed § 507.5(d) would provide that subpart C would not apply to a qualified facility, except as provided by subpart E (i.e., except as provided by the proposed provisions for withdrawal), and that qualified facilities are subject to the requirements in § 507.7.

5. Proposed § 507.2(e) and (f)—Exemption Applicable to Certain On-farm Manufacturing, Processing, Packing or Holding Food by a Small or Very Small Business

a. Requirements of section 103 of FSMA. As discussed in section VII.A.1, section 103(c)(1)(A) of FSMA requires that the Secretary publish a proposed rule to issue regulations with respect to ''(i) activities that constitute on-farm packing or holding of food that is not grown, raised, or consumed on such farm or another farm under the same ownership for purposes of section 415 of the [FD&C Act]; and (ii) activities that constitute on-farm manufacturing or processing of food that is not consumed on that farm or on another farm under common ownership for purposes of section 415.'' Section 103(c)(1)(B) of FSMA directs that the rulemaking ''shall enhance the implementation of such section 415 [of the FD&C Act] and clarify the activities that are included as part of the definition of the term ''facility'' under such section 415.'' In section VII, the Agency discusses clarifications of certain on-farm activities and whether they trigger the section 415 registration requirement in order to enhance the implementation of section 415 by clarifying the treatment of various activities for purposes of section 415, including activities conducted on farms.

In the proposed rule for preventive controls for human food (78 FR 3646), FDA proposed adding a new definition of the term ''Mixed-type facility'' to § 1.227. The proposed definition would also state that an example of such a facility is a ''farm mixed-type facility,'' which is an establishment that grows and harvests crops or raises animals, and may conduct other activities within the farm definition, but also conducts activities that require the establishment to be registered. Mixed-type facility would mean an establishment that engages in both activities that are exempt from registration under section 415 of the FD&C Act and activities that require the establishment to be registered. Because the specific classes of activities mentioned in FSMA section 103(c) are, by definition, on-farm activities that do not fall within the farm definition, Congress has explicitly directed FDA to engage in rulemaking addressing establishments that conduct activities that are outside the farm definition on farms. Accordingly, FDA proposed to define the term ''farm mixed-type facility'' to refer to these establishments (78 FR 3646).

As discussed in section VII.A.2, section 103(c)(1)(C) of FSMA requires that the Secretary conduct a science-based risk analysis of ''(i) specific types of on-farm packing or holding of food that is not grown, raised, or consumed on such farm or another farm under the same ownership, as such packing and holding relates to specific animal foods; and (ii) specific on-farm manufacturing and processing activities as such activities relate to specific foods that are not consumed on that farm or on another farm under common ownership.'' As discussed in section VII.B, consistent with the requirements of section 103(c)(1)(C) of FSMA the Agency has conducted a qualitative risk assessment related to activity/animal food combinations for the purpose of determining which activity/animal food combinations would be considered low risk.

Section 103(c)(1)(D)(i) of FSMA requires that, in issuing the regulations under section 103(c)(1)(A), ''the Secretary shall consider the results of the science-based risk analysis conducted under [section 103(c)(1)(C) of FSMA], and shall exempt certain facilities from the requirements in section 418 of the [FD&C Act] . . ., including hazard analysis and preventive controls, and the mandatory inspection frequency in section 421 of [the FD&C Act] . . . or modify the requirements in [sections 418 or 421 of the FD&C Act], as the Secretary determines appropriate, if such facilities are engaged only in specific types of on-farm manufacturing, processing, packing, or holding activities that the Secretary determines to be low risk involving specific foods the Secretary determines to be low risk.'' Section 103(c)(1)(D)(ii) of FSMA provides that ''[t]he exemptions or modifications under section 103(c)(1)(D)(i) of FSMA shall not include an exemption from the requirement to register under section 415 of the [FD&C Act] . . . if applicable, and shall apply only to small businesses and very small businesses, as defined in the regulation promulgated under section 418(n) of the [FD&C Act].''

b. FDA's interpretation of section 103(c)(1)(D)(i) of FSMA. FDA considers the language of section 103(c)(1)(D)(i) of FSMA to be unambiguous with regard to the reach of the exemption. The language of section 103(c)(1)(D)(i) includes the requirement ''if such facilities are engaged only in specific types of on-farm manufacturing, processing, packing, or holding activities that the Secretary determines to be low risk involving specific foods the Secretary determines to be low risk.'' FDA tentatively concludes that this language is unambiguous and means that Congress intended us to exempt a facility from, or modify the requirements of, section 418 of the FD&C Act under this authority if the facility only conducts a limited set of low-risk activity/animal food combinations that would otherwise be subject to section 418, that is, to the extent the facility is subject to section 418, it ''is engaged only in'' the identified activities involving the identified foods. This interpretation seems both protective of public health and consistent with the preventive purpose of section 418 of the FD&C Act. This interpretation would mean that a facility would be required to conduct a hazard analysis and establish and implement risk-based preventive controls for all activities conducted on all animal foods (including low-risk activity/animal food combinations) if a facility conducts a single activity subject to section 418 of the FD&C Act that is not a low-risk activity/animal food combination, unless the facility qualifies for another exemption from subpart C.

c. Proposed § 507.5(e)—Exemptions for on-farm low-risk packing or holding activity/food combinations. Proposed § 507.5(e) would provide that subpart C would not apply to on-farm packing or holding of animal food by a small or very small business if the only packing and holding activities subject to section 418 of the FD&C Act that the business conducts are the following low-risk packing or holding activity/animal food combinations on animal food not grown, raised, or consumed on that farm mixed-type facility or another farm or farm mixed-type facility under the same ownership:

1. Conveying, weighing, sorting, culling, or grading (incidental to storing):

- Grain (e.g., barley, corn, rice, oat, sorghum, triticale, wheat);
- Oilseed (e.g., cottonseed, linseed, rapeseed, soybean, sunflower);
- Grain or oilseed byproducts;
- Forage (e.g., hay or ensiled material); or
- Other plants or plant byproducts (e.g., almond, peanut, or soybean hulls, citrus, other fruit including culled fruit, potatoes, or other vegetables including culled vegetables).

2. Storing:

- Dried grain;
- Dried oilseed;
- Byproducts of dried grain or dried oilseed;

- Forage; or
- Other plants or plant byproducts.

3. Packing:

- Grain;
- Oilseed;
- Grain or oilseed byproducts;
- Forage; or
- Other plants or plant byproducts.

4. Mixing (incidental to packing or storing):

- Grain, whole; or
- Forage.

The low-risk on farm packing and holding activity/animal food combinations on food not grown, raised, or consumed on that farm mixed-type facility or another farm or farm mixed-type facility under the same ownership reflect the findings of the analysis required by section 103(c)(1)(C) of FSMA, discussed in sections VII.B and VII.C.

For purposes of proposed § 507.5(e) and (f), "other plant byproducts" includes such things as barley hulls, cottonseed hulls, corn cobs, oat hulls, rice hulls, and straw. Grain and oilseed byproducts can be considered part of "grain and oilseed" as a general matter, but FDA has addressed those foods separately for the purpose of the risk evaluation and the proposed § 507.5(e) and (f) exemptions in order to accurately reflect differences in activity/animal food combinations likely to be performed on farm mixed-type facilities on grain and oilseed byproducts as compared to other grains and oilseeds, as well as differences in risk across those activity/animal food combinations.

d. Proposed § 507.5(f)—Exemptions for on-farm low-risk manufacturing/processing activity/animal food combinations. Proposed § 507.5(f) would provide that subpart C would not apply to on-farm low-risk manufacturing/processing activities conducted by a small or very small business if the only manufacturing/processing activities subject to section 418 of the FD&C Act that the business conducts consists of the following:

1. When conducted on a farm/farm mixed-typed facility's own (those grown or raised on that farm/farm mixed-type facility or another farm/farm mixed-type facility under the same ownership) raw agricultural commodities for distribution into commerce:

- Cracking, crimping, flaking:
  - Grain (e.g., barley, corn, rice, oat, sorghum, triticale, wheat);
  - Oilseed (e.g., cotton seed, linseed, rapeseed, soybean, sunflower); or
  - Grain or oilseed byproducts.
- Crushing, grinding, milling, pulverizing, or dry rolling:
  - Grain;
  - Oilseed;
  - Grain or oilseed byproducts;
  - Forage (e.g., hay or ensiled material); or
  - Other plants or plant byproducts (e.g., such as almond, peanut, or soybean hulls, citrus, other fruit including culled fruit, potatoes, or other vegetables including culled vegetables).
- Making silage.
- Chopping, or shredding hay.
- Extracting (mechanical) or wet rolling:
  - Grain; or
  - Oilseed.

2. When conducted on animal food other than the farm mixed-typed facility's own raw agriculture commodities for distribution into commerce:

- Cracking, crimping, flaking, or shelling:
  - Grain (e.g., barley, corn, rice, oat, sorghum, triticale, wheat);
  - Oilseed (e.g., cotton seed, linseed, rapeseed, soybean, sunflower); or
  - Grain or oilseed byproducts.
- Crushing, grinding, milling, pulverizing, or dry rolling:
  - Grain;
  - Oilseed;
  - Grain or oilseed byproducts;
  - Forage (e.g., hay or ensiled material); or
  - Other plants or plant byproducts (e.g., such as almond, peanut, or soybean hulls, citrus, other fruit including culled fruit, potatoes, or other vegetables including culled vegetables).
- Making silage.
- Chopping or shredding hay.
- Extracting (mechanical) or wet rolling:
  - Grain; or
  - Oilseed.
- Labeling:
  - Grain whole; or
  - Oilseed whole.
- Sifting, separating, or sizing:
  - Grain;
  - Oilseed;
  - Grain or oilseed byproducts; or
  - Other plants or plant byproducts.

The low-risk on-farm manufacturing/processing activity/animal food combinations reflect the findings of the analysis required by section 103(c)(1)(C) of FSMA, discussed in sections VII.B and VII.C.

6. Proposed § 507.5(g) and (h)—Exemptions Applicable to Raw Agricultural Commodities (RACs)

In § 507.5(g), the Agency is proposing that subpart C would not apply to facilities solely engaged in the storage of raw agricultural commodities (other than fruits and vegetables) intended for further distribution or processing. And in § 507.5(h), the Agency is proposing that subpart B would not apply to the holding or transportation of one or more "raw agricultural commodities," as defined in section 201(r) of the FD&C Act.

The current 21 CFR 110.19(a) for human food, provides that establishments engaged solely in the harvesting, storage, or distribution of one or more RACs, which are ordinarily cleaned, prepared, treated, or otherwise processed before being marketed to the consuming public, are exempt from the requirements of part 110 (21 CFR part 110). In section VIII.D of the document for the proposed rule for preventive controls for human food (78 FR 3646), the Agency discusses the meaning of the term raw agricultural commodity. The Agency tentatively concludes that the exemption for RACs from proposed part 507 subpart B for animal food is consistent with the treatment of RACs for human food.

Section 418(m) of the FD&C Act provides in relevant part that FDA may by regulation "exempt or modify the requirements for compliance under [section 418 of the FD&C Act] with respect to facilities that are solely engaged in . . . the storage of raw agricultural commodities (other than fruits and vegetables) intended for further distribution or processing".

This provision would exempt, for example, facilities that only store whole grains (such as corn, wheat, barley, oats, and soybeans) for animal food from subpart C. This would include facilities such as grain elevators provided that such facilities do not conduct other activities subject to section 418 of the FD&C Act. Outbreaks of illness associated with feeding RACs to animals have not been traced back to storage facilities solely engaged in the storage of RACs. In addition, facilities that are solely engaged in the storage of RACs are exempt from the current part 110 CGMP regulations for human food, and FDA proposes to also exempt these facilities from the proposed CGMPs for animal food. Such facilities would remain subject to the requirements of the FD&C Act. For example, if animal food is stored under insanitary conditions whereby the animal food may become contaminated with filth or rendered injurious to health, the animal food would be adulterated under section 402(a)(4) of the FD&C Act.

While outbreaks of illness associated with feeding RACs to animals have not been traced back to storage facilities solely engaged in the storage of RACs, FDA is aware of changes in feeding practices which might increase the risk associated with feeding RACs obtained directly from storage facilities. FDA is aware that some farms function as animal feeding operations, growing no crops for animal food use, but simply purchasing animal food, raw agricultural commodities, or animal food ingredients for further manufacturing into animal food for animals held on that farm. In the animal food industry, raw agriculture commodities such as corn, wheat, oats, barley, rye, milo, rice, soybeans, peanuts, and canola are shipped directly from grain elevators to farms that raise animals for human food production such as poultry farms (broilers, layers), dairy farms, beef-feed lots, and swine farms. At these farms, the raw agricultural commodity received from the grain elevators is mixed (processed) into animal food rations.

While the Agency tentatively concludes that animal food facilities such as grain elevators that are solely engaged in the storage of grains that are raw agricultural commodities should be exempt from proposed subpart B and proposed subpart C, the Agency does have some concerns. One of those concerns is the potential for mycotoxins, such as aflatoxins, fumonisins, and DON, to be present in RACs obtained by farms and fed to animals. This concern is largely mitigated for RACs intended for human food because RACs for human food routinely undergo further processing and are rarely consumed in the ''raw'' state.

Mycotoxins are toxic by-products of mold that can develop in certain agricultural commodities pre-harvest or post-harvest while in storage. Mycotoxins can reduce animal productivity, cause sudden death if fed in large quantities, and can become a component of milk and eggs intended for human consumption.

Mycotoxin contamination varies greatly from year to year and by geographic region of the country, depending on weather conditions that stress crops and predispose to mold growth. In regions of the country where conditions tend to favor mold growth, grain elevators and other buyers routinely monitor for this hazard and turn away producers whose crops exceed FDA's action levels for the various mycotoxins. For example, grain elevators will reject corn that tests higher than 20 parts per billion for aflatoxin, the action level established by FDA for use in feed for animal species other than beef cattle, swine, poultry, or when the intended species is not known. Grain elevators in other regions of the country are familiar with the weather phenomena that predispose to mycotoxin production and monitor incoming shipments of grain accordingly. The grain industry is also familiar with proper drying and storing procedures to prevent mold growth and mycotoxin production. Therefore, due to controls already in place by the grain industry, and due to regulatory oversight by USDA under the United States Grain Standards Act, FDA has tentatively concluded to exempt facilities solely holding grains from preventive controls.

However, the Agency is seeking comment on whether animal food facilities, such as grain elevators, that are solely engaged in the storage of grains that are raw agricultural commodities should be exempt from subpart B and subpart C of proposed part 507; how many of these types of facilities and operations are in the United States; and what is the best approach to ensure that the raw agricultural commodities distributed by these facilities to animal feeding operations are free of hazards that would be likely to cause illness or injury to animals or humans.

7. Applicability of Part 507 to Alcoholic Beverages

In the proposed rule for preventive controls for human food (78 FR 3646), the Agency is proposing that proposed subpart C, ''Hazard Analysis and Risk-Based Preventive Controls,'' would not apply to certain alcoholic beverages and a very narrow set of prepackaged other food at alcoholic beverage facilities, based on the Agency's interpretation of section 116 of FSMA. Under proposed § 117.5(i), subpart C of the human food rule would not apply with respect to food that is not an alcoholic beverage at certain alcoholic beverage facilities, provided that such food (1) is in prepackaged form that prevents any direct human contact with such food, and (2) constitutes not more than 5 percent of the overall sales of the facility, as determined by the Secretary of the Treasury (see section X.C.7 of the document for the proposed rule for preventive controls for human food (78 FR 3646)). Section 116 of FSMA applies to animal food. However, the Agency is not aware of any animal food at alcoholic beverage facilities that would be exempt from section 418 of the FD&C Act under the proposed interpretation, and therefore is not aware of any animal food at alcoholic beverage facilities that would be exempt from proposed subpart C, ''Hazard Analysis and Risk-Based Preventive Controls,'' for animal food. For example, FDA understands that many breweries and distilleries sell spent grains, such as brewers dried grains and distillers dried grains, as animal food. Because those spent grains are not alcoholic beverages themselves, and they are not in a prepackaged form that prevents any direct human contact with the food, the Agency tentatively concludes that subpart C of this proposed rule would apply to them.

D. Proposed § 507.7—Requirements That Apply to a Qualified Facility

1. Requirements of Section 418(l) of the FD&C Act

Section 418(l) of the FD&C Act establishes modified requirements for ''qualified facilities.'' As discussed in section II.C, section 418(l)(1) of the FD&C Act establishes the conditions for a facility to be a ''qualified facility'' based on either business size (section 418(l)(1)(B) of the FD&C Act) or a combination of the average monetary value of the food sold and the value of food sold to qualified end users as compared to all other purchasers (section 418(l)(1)(C) of the FD&C Act), and proposed § 507.3 would establish a definition for ''qualified facility'' based on section 418(l)(1).

Sections 418(l)(2)(A) and (B) of the FD&C Act provide that a qualified facility is exempt from the requirements of sections 418(a) through (i) and (n) of the FD&C Act (i.e., the requirements for hazard analysis and risk-based preventive controls), but must instead submit two types of documentation to the Secretary of HHS. The first type of required documentation relates to food safety practices at the facility, and section 418(l)(2)(B)(i) of the FD&C Act provides two options for satisfying this documentation requirement. Under section 418(l)(2)(B)(i)(I) of the FD&C Act, the qualified facility may choose to submit documentation that demonstrates that the owner, operator, or agent in charge of the facility has identified potential hazards associated with the food being produced, is implementing preventive controls to address the hazards, and is monitoring the preventive controls to ensure that such controls are effective. Alternatively, under section 418(l)(2)(B)(i)(II) of the FD&C Act, the qualified facility may choose to submit documentation (which may include licenses, inspection reports, certificates, permits, credentials, certification by an appropriate agency (such as a State department of agriculture), or other evidence of oversight), as specified by the Secretary, that the facility is in compliance with State, local, county, or other applicable non-Federal food safety law.

The second type of required documentation relates to whether the facility satisfies the definition of a qualified facility. Under section 418(l)(2)(B)(ii) of the FD&C Act, the facility must submit documentation, as specified by the Secretary in a guidance document, that the facility is a qualified facility under section 418(l)(1)(B) of the FD&C Act or section 418(l)(1)(C) of the FD&C Act.

Section 418(l)(7)(A) of the FD&C Act requires that a qualified facility that is exempt from the requirements under sections 418 (a) through (i) and subsection (n), and that does not prepare documentation under section 418(l)(2)(B)(i)(I)of the FD&C Act, provide notification to consumers by one of two procedures, depending on whether a food packaging label is required on the food. With respect to an animal food for which an animal food packaging label is required by the Secretary of HHS under any other provision of the FD&C Act, section 418(l)(7)(A)(i) of the FD&C Act requires that a qualified facility include prominently and conspicuously on such label the name and business address of the facility where the food was manufactured or processed. With respect to an animal food for which an animal food packaging label is not required by the Secretary of HHS under any other provisions of the FD&C Act, section 418(l)(7)(A)(ii) of the FD&C Act requires that a qualified facility prominently and conspicuously display, at the point of purchase, the name and business address of the facility where the food was manufactured or processed, on a label, poster, sign, placard, or documents delivered contemporaneously with the food in the normal course of business, or, in the case of Internet sales, in an electronic notice.

2. Proposed § 507.7(a)—Documentation To Be Submitted

a. Proposed § 507.7(a)(1)—Documentation That the Facility Is a Qualified Facility

Proposed § 507.7(a)(1) would require that a qualified facility submit to FDA documentation that the facility is a qualified facility. Consistent with the conditions in section 418(l)(1) of the FD&C Act for a facility to be a qualified facility, and the Agency's proposed definition (proposed § 507.3) of "qualified facility," the documentation would be directed to either the status of the facility as a very small business (as would be defined in proposed § 507.3) or the applicability of conditions for average annual monetary value and the value of food sold to qualified end users as compared to other purchasers (as would be included in the definition of qualified facility in proposed § 507.3). As discussed further in section VIII.D.5, FDA tentatively concludes that a statement from the owner, operator, or agent in charge of a qualified facility certifying that the facility is a very small business, otherwise meets the definition of a qualified facility under proposed § 507.3, or both, would be acceptable for the purposes of satisfying the requirements that would be established in proposed § 507.7(a)(1). The Agency would not, for example, require that a facility submit financial information to FDA demonstrating its total sales or to the proportion of sales to qualified end users.

Proposed § 507.7(a)(1) also would establish that, for the purpose of determining whether a facility satisfies the definition of qualified facility, the baseline year for calculating the adjustment for inflation is 2011. The conditions related to average annual monetary value established in section 418(l)(1)(C) of the FD&C Act, and the definition of very small business in proposed § 507.3, allow adjustment for inflation. To establish a level playing field for all facilities that may satisfy definition of a qualified facility, the Agency is proposing to establish the baseline year for the calculation in proposed § 507.7(a)(1). The Agency is proposing to establish 2011 as the baseline year for inflation because 2011 is the year that FSMA was enacted into law. The Agency tentatively concludes that because Congress provided a specific dollar amount in section 418(l)(1)(C)(ii)(II) of the FD&C Act, i.e., $500,000, and it provided that the dollar amount should be adjusted for inflation, it is reasonable to establish the baseline year as the year that the law was enacted.

b. Proposed § 507.7(a)(2)—Documentation Related to Food Safety Practices at a Facility

Proposed § 507.7(a)(2) would provide two options for satisfying the documentation requirement in section 418(l)(2)(B)(i) of the FD&C Act related to food safety practices at the facility. Proposed § 507.7(a)(2)(i) would allow qualified facilities to submit documentation to demonstrate that the owner, operator, or agent in charge of the facility has identified the potential hazards associated with the food being produced, is implementing preventive controls to address the hazards, and is monitoring the performance of the preventive controls to ensure that such controls are effective to satisfy this requirement.

Proposed § 507.7(a)(2)(i) would implement the provisions of section 418(l)(2)(B)(i)(I) of the FD&C Act, except that proposed § 507.7(a)(2)(i) would specify monitoring the performance of the preventive controls to ensure that such controls are effective (emphasis added). As discussed in section II.C, under the overall framework of the proposed requirements that would be established in subpart C, monitoring is directed to performance of preventive controls. Thus, proposed § 507.7(a)(2)(i) is consistent with the statute and the overall framework of this proposed rule.

Proposed § 507.7(a)(2)(ii) would provide another option for satisfying the documentation requirement in section 418(l)(2)(B)(i) of the FD&C Act related to food safety practices at the facility by allowing qualified facilities to submit documentation (which may include licenses, inspection reports, certificates, permits, credentials, certification by an appropriate agency (such as a State department of agriculture), or other evidence of oversight), that the facility is in compliance with State, local, county, or other applicable non-Federal food safety law, including relevant laws and regulations of foreign countries. Proposed § 507.7(a)(2)(ii) would implement the provisions of section 418(l)(2)(B)(i)(II) of the FD&C Act.

FDA tentatively concludes that a statement from the owner, operator, or agent in charge of a qualified facility certifying that the facility: (1) Has identified the potential hazards associated with the animal food being produced, is implementing preventive controls to address the hazards, and is monitoring the implementation of the preventive controls to ensure that such controls are effective or (2) that the facility is in compliance with State, local, county, or other applicable non-Federal food safety law, including relevant laws and regulations of foreign countries, would be acceptable for the purposes of satisfying the requirements that would be established in proposed § 507.7(a)(2). The Agency would not, for example, require that a facility submit documentation to FDA demonstrating the content of their hazard identification, preventive controls, or monitoring of the implementation of preventive controls; or copies of their non-Federal licenses, inspection reports, certificates, permits, credentials, or certifications.

3. Proposed § 507.7(b)—Procedure for Submission

Proposed § 507.7(b) would require that qualified facilities submit the documentation that would be required by proposed § 507.7(a) by one of two procedures. Proposed § 507.7(b)(1) would provide an option to submit documentation electronically at *http://www.access.fda.gov* by following the instructions to be provided on that Web page. Proposed § 507.7(b)(1) would inform facilities that this Web site is available from wherever the Internet is accessible, including libraries, copy centers, schools, and Internet cafes. Although electronic submission is not required, proposed § 507.7(b)(1) would encourage electronic submission, which is efficient for FDA and should also be efficient for facilities. Electronic submission generally would be available 24 hours a day, 7 days a week, unless the Web site is experiencing technical difficulties or is undergoing maintenance.

Proposed § 507.7(b)(2) would provide an option to submit documentation by mail. A qualified facility would have the option to submit documents in a paper format or in an electronic format on a CD–ROM, by mail to the U.S. Food and Drug Administration, ATTN: Qualified Facility Coordinator, 10903 New Hampshire Ave., Silver Spring, MD 20993. "Mail" would include the U.S. mail and businesses that can deliver documents to the address provided. The Agency would recommend that an owner, operator or agent in charge of a qualified facility submit by mail only if the qualified facility does not have reasonable access to the Internet. It is not efficient for FDA to receive such documents by mail.

The Agency is not proposing to provide for submission by fax. The Agency expects that there may be technical difficulties or loss or mix-up of some submitted information if the Agency were to allow for submission by fax.

4. Proposed § 507.7(c)—Frequency of Submission

Proposed § 507.7(c)(1) would require that the documentation that would be required by section § 507.7(a) be submitted to FDA initially within 90 days of the applicable compliance date of the rule. As discussed in section VI, the compliance date for a small business would be 2 years after the date of publication of the final rule and the compliance date for a very small business would be 3 years after the date of publication of the final rule.

Proposed § 507.7(c)(2) would require that the documentation that would be required by proposed § 507.7(a) also must be resubmitted to FDA at least every 2 years, or whenever there is a material change to the information that would be described in proposed § 507.7(a). For the purposes of proposed § 507.7, a material change would be one that changes whether or not a facility is a "qualified facility." The status of a facility as a qualified facility has the potential to change materially on an annual basis. For example, if a facility reports that it is a very small business (i.e., under one option identified in proposed § 507.3, has less than $500,000 in total annual sales of animal food, adjusted for inflation), its total annual sales of animal food likely would change on an annual basis, and could change so as to exceed $ 500,000. Likewise, if a facility reports that it otherwise satisfies the definition of a qualified facility, its total annual sales of animal food and value of animal food sold to qualified end users as compared to other purchasers likely would change on an annual basis, and could change so as to no longer satisfy the definition of a qualified facility.

5. Information That Would Be Submitted

Consistent with section 418(l)(2)(B)(ii) of the FD&C Act, the Agency intends to issue guidance regarding documentation that would be submitted under proposed § 507.7(a)(1) to demonstrate that a facility is a qualified facility. As discussed in sections VIII.D.2.a and VIII.D.2.b, the Agency tentatively concludes that certified statements from the owner, operator, or agent in charge of a qualified facility would be acceptable for the purposes of satisfying the requirements that would be established in proposed § 507.7(a)(1) and (a)(2).

To inform the guidance required under section 418(l)(2)(B)(ii) of the FD&C Act and any other guidance that may be useful in addressing questions regarding submission of documentation under this subpart, in this document the Agency requests comment on an option it is considering regarding the submission of documentation. Specifically, the Agency requests comment on the efficiency and practicality of submitting the required documentation using the existing mechanism for registration of food facilities, with added features to enable a facility to identify whether or not the facility is a qualified facility. A facility that does not identify itself as a qualified facility would not be prompted to provide additional information under proposed § 507.7(a).

A facility that identifies itself as a qualified facility would be prompted to provide the following information by checking items that apply. Such items could include:

- Whether the facility satisfies the conditions for a qualified facility:
  - ○ As a very small business as that term would be defined in proposed § 507.3;
  - ○ As a facility that otherwise satisfies the definition of qualified facility in proposed § 507.3 based on average monetary value of sales and value of animal food sold to qualified end users as compared to other purchasers; or
  - ○ Both of the conditions.
- Whether the facility:
  - ○ Has identified the potential hazards associated with the animal food being produced, is implementing preventive controls to address the hazards, and is monitoring the implementation of the preventive controls to ensure that such controls are effective;
  - ○ Is in compliance with State, local, county, or other applicable non-Federal food safety law, including relevant laws and regulations of foreign countries; or
  - ○ Both of the conditions.

In essence, such a system would provide for self-certification that the facility has appropriate information demonstrating that the facility is a qualified facility and either has identified the potential hazards associated with the food being produced, is implementing preventive controls to address the hazards, and is monitoring the implementation of the preventive controls to ensure that such controls are effective; or is in compliance with State, local, county, or other applicable non-Federal food safety law, including relevant laws and regulations of foreign countries. Such a system may include a statement reminding submitters that anyone who makes a materially false, fictitious, or fraudulent statement to the U.S. Government is subject to criminal penalties under 18 U.S.C. 1001. Using such a system, a qualified facility could update the documentation required by proposed § 507.7(a) during the biennial registration required by section 415(a)(3) of the FD&C Act.

6. Proposed § 507.7(d)—Notification to Consumers

Proposed § 507.7(d) would require that a qualified facility that does submit the type of documentation directed to food safety practices described in § 507.7(a)(2)(i) provide notification to consumers as to the name and complete business address of the facility where the animal food was manufactured or processed (including the street address or P.O. box, city, State, and zip code for domestic facilities, and comparable full address information for foreign facilities) consistent with section 418(l)(7) of the FD&C Act. If an animal food packaging label is required, proposed § 507.7(d)(1) would require that the required notification appear prominently and conspicuously on the label of the animal food. If an animal food packaging label is not required, proposed § 507.7(d)(2) would require that the required notification appear prominently and conspicuously, at the point of purchase, on a label, poster, sign, placard, or documents delivered contemporaneously with the animal food in the normal course of business, or in an electronic notice, in the case of Internet sales.

Proposed § 507.7(d) would enable consumers to contact the facility where an animal food was manufactured or processed (e.g., if the consumer identifies or suspects a food safety problem with a product) irrespective of whether the animal food product bears a label. The use of the term ''business address'' in section 418(l)(7) of the FD&C Act contrasts with Congress' use of a different term, ''place of business,'' in section 403(e) of the FD&C Act (21 U.S.C. 343(e)). Section 403(e) provides that foods in package form are misbranded unless the product label bears the name and place of business of the manufacturer, packer, or distributor of the food. The Agency's regulations interpret ''place of business'' as requiring only the firm's city, state, and zip code to appear on the product label, as long as the firm's street address is listed in a current telephone directory or other city directory (21 CFR 501.5(d)). The Agency tentatively concludes that the use of the term ''business address'' in section 418(l)(7) demonstrates Congress' intent to require the facility's full address, including the street address or P.O. box, to appear on labels or other required notifications when the facility has opted to not submit documentation directed to food safety practices under section 418(l)(2)(B)(i)(I) of the FD&C Act. If Congress had considered the less complete address already required under section 403(e)(1) of the FD&C Act and the ''place of business'' labeling regulation (§ 501.5(d)) to be adequate for notification to consumers for animal foods required to bear labels, there would have been no need to impose a new, more specific requirement in section 418(l)(7) for the facility's ''business address'' to appear on the food label. When proposed § 507.7(d) would apply to an animal food for which a food packaging label is required under any other provision of the FD&C Act, the complete business address would substitute for the ''place of business'' required under section 403(e)(1) of the FD&C Act and § 501.5(d) and would not impose any requirement for a label that would be in addition to any label required under any other provision of the FD&C Act. The Agency asks for comment on this interpretation.

7. Records

Proposed § 507.7(e) would require that a qualified facility maintain records relied upon to support the documentation that would be required by § 507.7(a). Proposed § 507.7(a) would not require that a qualified facility establish any new records, but merely retain those that the facility relied upon to support the documentation that would be required by proposed § 507.7(a). Proposed § 507.7(e) would establish that the records that a qualified facility must maintain are subject to the requirements of subpart F of part 507. As discussed in section XII, proposed subpart F would provide the general requirements that apply to all records required to be established and maintained by proposed part 507, including provisions for retention of records and for making records available for official review. Together, proposed § 507.7(a) and (b) would make the underlying records qualified facilities would rely on to support their self-certifications available to FDA upon request. The Agency tentatively concludes that it is appropriate to require that the records relied upon to support a self-certified statement be retained and made available to FDA upon request.

E. Proposed § 507.10—Applicability of Subpart C to a Facility Solely Engaged in the Storage of Packaged Animal Food That Is Not Exposed to the Environment

1. Requirements of Section 418 of the FD&C Act

Section 418(m) of the FD&C Act provides, in relevant part, that ''[t]he Secretary may, by regulation, exempt or modify the requirements for compliance under [section 418 of the FD&C Act] with respect to facilities that are solely engaged in . . . the storage of packaged foods that are not exposed to the environment.''

2. Petition Relevant to Section 418(m) of the FD&C Act

In a letter dated July 22, 2011, an industry coalition of the American Bakers Association, the American Frozen Food Institute, the Grocery Manufacturers Association, the International Bottled Water Association, the International Dairy Foods Association, the International Warehouse Logistics Association, the Peanut and Tree Nut Processors Association, and the Snack Food Association (the section 418(m) petitioners) submitted a citizen petition (Docket No. FDA–2011–P–0561). The petition requests that FDA issue regulations under section 418(m) of the FD&C Act ''to exempt from compliance or modify the requirements for compliance under section 418 [of the FD&C Act] for facilities that are solely engaged in the storage of packaged foods that are not exposed to the environment, by allowing such facilities to satisfy the requirements of that section through compliance with the [CGMPs] mandated for such facilities by [current] § 110.93.'' For full discussion of this petition, please see the discussion in section X.D of the document for the proposed rule for preventive controls for human food (78 FR 3646).

3. FDA's Tentative Response to the Petition

The Agency tentatively agrees in part, and disagrees in part, with the section 418(m) petitioners. As discussed more fully in the paragraphs that follow, FDA agrees that it is appropriate for facilities solely engaged in the storage of unexposed packaged animal food to be exempt from the requirements that would be established in proposed subpart C, provided that the animal food does not require time/temperature control for safety. For unexposed packaged animal food that requires time/temperature control for safety, FDA disagrees that such an exemption is warranted, but tentatively concludes that unexposed packaged animal food that requires time/temperature control for safety could be subject to modified requirements rather than to the full requirements that would be established in proposed subpart C.

The Agency disagrees that warehouse operators do not have access to information relevant to conducting a hazard analysis and establishing risk-based preventive controls. The principal hazard that would be identified in any hazard analysis for unexposed packaged animal food is the potential for the growth of, or toxin formation by, microorganisms of animal or human health significance when an unexposed refrigerated packaged animal food requires time/temperature control for safety. Information about this hazard and appropriate preventive controls for this hazard is widely available (Refs. 39, 40, and 41). For example, the 2009 Edition of FDA's Food Code defines ''Potentially Hazardous Food (Time/Temperature Control for Safety Food)'' as a food that requires time/temperature control for safety to limit pathogenic microorganism growth or toxin formation (Ref. 39). Earlier editions (e.g., the 2001 Food Code) included a similar definition for ''potentially hazardous food''; since 2005, the definition jointly refers to ''potentially hazardous food'' and ''time/temperature control for safety food'' (commonly referred to as TCS food) to emphasize the importance of temperature control in keeping food safe. Although FDA disagrees that warehouse operators do not have access to information relevant to conducting a hazard analysis and establishing risk-based preventive controls, the Agency agrees that it is not necessary for each facility solely engaged in the storage of unexposed packaged animal food to conduct its own hazard analysis to identify this hazard for unexposed refrigerated packaged animal food as reasonably likely to occur and for each such facility to determine that time/temperature control is the appropriate preventive control.

FDA also disagrees that proposed § 507.28 alone would be adequate for addressing environmental problems such as a flood in the facility and pest control problems, even though the animal food in question is not exposed to the environment and pest control problems with the container would likely be visible to the warehouse operator. However, FDA tentatively concludes that proposed § 507.28, along with other applicable provisions of proposed part 507, subpart B, such as pest control in proposed § 507.19, do adequately address most safety-related issues that may arise in facilities solely engaged in the storage of unexposed packaged animal food. FDA disagrees that proposed § 507.28, or other provisions in proposed part 507, subpart B, justifies the exemption from all preventive control requirements sought by the petitioners in the specific case of unexposed refrigerated packaged animal food that requires time/temperature control for safety (later in this document stated as unexposed refrigerated packaged TCS animal food). As discussed more fully in section X.I, such animal food requires the implementation of an appropriate preventive control (temperature), monitoring that control, taking corrective actions when there is a problem with that control, verifying that the control is consistently implemented, and establishing and maintaining records documenting the monitoring, corrective actions, and verification. FDA tentatively concludes that it is appropriate to distinguish between packaged animal food that requires such time/temperature control and packaged animal food that does not.

FDA also disagrees that an exemption provided under section 418(m) of the FD&C Act should be established in a manner that has the potential to be interpreted more broadly than section 418(m) provides. The section 418(m) petitioners request that FDA establish a provision that ''A facility that is engaged solely in the storage, holding, warehousing, or distribution of packaged foods that are not exposed to the environment shall be exempt from the requirements of section 418 [of the FD&C Act]'', whereas section 418(m) provides discretion for an exemption ''with respect to facilities that are solely engaged in . . . the storage of packaged foods that are not exposed to the environment.'' Under proposed § 507.3, ''holding'' would mean storage of animal food, and holding facilities would include, relevant to unexposed packaged animal food, warehouses and cold storage facilities. To the extent that a facility that is engaged solely in ''warehousing'' or ''distribution'' of unexposed packaged animal food is merely ''storing'' or ''holding'' the animal food, an exemption established using the language provided by section 418(m) would apply to that facility. However, to the extent that a facility that is engaged solely in ''warehousing'' or ''distribution'' of unexposed packaged animal food is not merely ''storing'' or ''holding'' the animal food, an exemption established using the language provided by section 418(m) would not apply to that facility.

In response to the petition, FDA is proposing to establish an exemption from subpart C for facilities solely engaged in the storage of unexposed packaged animal food (proposed § 507.10). FDA also is proposing to establish modified requirements at such facilities to require that the owner, operator, or agent in charge of such a facility comply with modified requirements for any unexposed refrigerated packaged TCS animal food (proposed § 507.48). See the discussion of proposed § 507.10 in the next section and the discussion of proposed § 507.48 in section X.I.

4. Proposed § 507.10—Applicability of Part 507 to a Facility Solely Engaged in the Storage of Packaged Animal Food That Is Not Exposed to the Environment

Proposed § 507.10(a) would provide that subpart C does not apply to a facility solely engaged in the storage of packaged animal food that is not exposed to the environment. Proposed § 507.10(b) would establish that unexposed packaged animal food at such facilities is subject to modified requirements that would be established in proposed § 507.48. As discussed more fully in section X.I, the modified requirements would mandate that such a facility establish and implement appropriate temperature controls, monitor the temperature controls, take corrective actions, verify that the temperature controls are consistently implemented, and establish and maintain records documenting the monitoring, corrective actions, and verification activities for unexposed refrigerated packaged TCS animal food. These modified requirements would be a subset of the proposed requirements that would be established in subpart C.

There are limited routes of contamination for unexposed packaged animal food in a facility that solely stores unexposed packaged animal food (e.g., packaged animal food in containers in a warehouse). Contamination can occur, for example, if rodents gnaw through packages or if human waste from an improperly maintained toilet facility spills and seeps into paper-based packaging. However, with one exception, the CGMP requirements in proposed subpart B (e.g., proposed §§ 507.17, 507.19, 507.20, and 507.28) would apply to the storage of unexposed packaged animal food and be adequate to prevent such contamination so that it would not be necessary for the owner, operator, or agent in charge of a facility to address these routes of contamination by applying the hazard analysis and risk-based preventive controls that would be established in proposed subpart C. The exception would be for the rare circumstances in which RACs are packaged in a manner in which the RACs are not exposed to the environment. An establishment solely engaged in storing RACs would be exempt from CGMPs in proposed subpart B. Such an establishment would continue to be subject to section 402(a)(4) of the FD&C Act. An establishment that is solely engaged in the storage of packaged RACs that are not exposed to the environment may find the provisions of proposed subpart B helpful in ensuring compliance with section 402(a)(4) of the FD&C Act.

Many of the requirements that would be established in proposed subpart C would be directed to manufacturing, processing, and packing animal food and would not apply to the storage of unexposed packaged animal food that does not require time/temperature control for safety. This is the case for:

- Process controls (proposed § 507.36(d)(1));
- Sanitation controls (proposed § 507.36(d)(2));

- Monitoring of process controls and sanitation controls (proposed § 507.39);
- Corrective actions (proposed § 507.42);
- Verification (including initial validation) of process controls (proposed § 507.45); and
- A recall plan (proposed § 507.38) (recalls generally are initiated by the manufacturer, processor, or packer of the animal food).

FDA tentatively concludes that the outcome of a hazard analysis for storage of unexposed packaged animal food that does not require time/temperature control for safety is that there are no hazards reasonably likely to occur. FDA also tentatively concludes that there would be little animal and human health benefit to requiring the owner, operator, or agent in charge of each facility solely engaged in the storage of such animal food to conduct its own hazard analysis and document that outcome in its own animal food safety plan. Likewise, FDA tentatively concludes that there would be no need for the facility to establish and implement preventive controls, with corresponding monitoring, corrective actions, or verification (including validation), because there would be no hazards reasonably likely to occur to trigger such activities. FDA also tentatively concludes that there would be no need for a qualified individual to conduct activities such as preparing the animal food safety plan (proposed § 507.30(c)); validating the preventive controls (proposed § 507.45(a)); reviewing records for implementation and effectiveness of preventive controls and appropriateness of corrective actions (proposed § 507.45(c)); or performing reanalysis of the animal food safety plan (proposed § 507.45(e)(4)), because the facility would not need to conduct these activities. Thus, with the exception of the unexposed refrigerated packaged TCS animal food, FDA tentatively concludes that the animal food safety system that would be established in proposed subpart C is not needed to significantly minimize or prevent the occurrence of hazards that could affect unexposed packaged animal food at a facility solely engaged in the storage of such animal food.

The purpose of proposed § 507.10(b) is to make clear that although a facility solely engaged in the storage of unexposed packaged animal food is exempt from subpart C, such a facility is subject to modified requirements that would be established in proposed § 507.48. These requirements would apply to the storage of unexposed refrigerated packaged TCS animal food. The Agency explains the basis for those proposed requirements in section X.I.

IX. Proposed Subpart B—Current Good Manufacturing Practice

A. Animal Food and Current Good Manufacturing Practices (CGMPs)

The preventive controls system will result in controls that are specific to each facility based on the hazards it identifies and the controls it determines are necessary to control such hazards. Although FDA has had general baseline controls that apply to most establishment manufacturing, processing, packing, and holding human food in its current good manufacturing regulations under part 110, FDA has not had such baseline controls for facilities manufacturing, processing, packing, and holding animal food. The animal food industry, as well as governmental entities and international bodies, have recognized the need for basic safety and sanitation measures that apply across the board to facilities handling animal food. The AAFCO passed its ''Model Good Manufacturing Practice Regulations for Feed and Feed Ingredients'' in August 2009 and published them in 2010 in the AAFCO *Official Publication* (Ref. 42). AAFCO is a voluntary membership association of State and Federal Agencies charged with the regulation, sale, and distribution of animal feeds. The goal of AAFCO is to provide a mechanism for developing and implementing uniform and equitable laws, regulations, standards, definitions, and enforcement policies for regulating the manufacture, labeling, distribution, and sale of animal feeds. AAFCO's Model CGMPs stipulate basic requirements for the production of safe animal food, and cover the following areas: Personnel; establishments, including construction, design, and grounds; maintenance and housekeeping, including pest control; equipment, including construction and design; receiving and storage for further manufacture; manufacturing; labeling; storage of finished feed and/or feed ingredients; inspection, sampling, and testing of incoming and finished feed and/or feed ingredients for adulterants; transportation of feed and/or feed ingredients; and voluntary recall/withdrawal. AAFCO is not an enforcement agency, however in States that adopt the model CGMPs into their State animal feed regulations, failure of an animal food facility to adhere to these CGMPs would be grounds for enforcement action by the state.

The Codex Animal Production and Health Manual of Good Practices for the Feed Industry is a collaborative effort between the Food and Agriculture Organization (FAO) of the United Nations, and the International Feed Industry Federation, with significant contributions from members of a number of national feed industry trade associations, members of individual companies within the feed industry, and animal feed experts from universities. The good manufacturing practices (GMPs) described in Section 3 (Ref. 43) of the manual are practices and procedures intended to ensure the safety and suitability of animal food throughout the feed chain, and provide for such practices and procedures to be implemented in the following areas: Buildings and facilities; location of feed establishment; design and layout; internal structure and fittings; water supply; cleaning facilities; air quality, temperature and ventilation; lighting; equipment; personal hygiene; cleaning; maintenance; pest control; waste; drains; storage; transport; and training.

The Prerequisite Programmes for Food Safety in the Manufacture of Food and Feed for Animals (Publicly Available Specification (PAS) 222) (Ref. 44) were prepared by the British Standard Institution and the PAS 222 Steering Group, with sponsorship by Safe Supply of Affordable Food Everywhere. The British Standard Institution is an independent, private, non-governmental, non-industry organization that develops standards for a variety of industries. It is the standards setting body of the United Kingdom (Ref. 44). The steering group was made up of members from Agriculture Industries Confederation, Cargill, FAO, Foundation for Food Safety Certification, Land O'Lakes, Nestle, and Nutreco. PAS 222 specifies requirements addressing the following areas: Site and associated utilities; processes, including workspaces and employee facilities; supplies of air, water, and other utilities; supporting services, including waste disposal; suitability of equipment and accessibility for cleaning, maintenance, and preventive maintenance; management of ingredients; management of medications; measures for the prevention of contamination; sanitation; pest control; personnel hygiene; rework; product withdrawal procedures; warehousing and transportation; formulation of products; specifications for services; training and supervision of personnel; product information; and food defense, biovigilance, and bioterrorism.

The GMPs described previously are the product of efforts by government, industry, and international animal health organizations. They are very similar to each other and similar to the CGMPs that FDA is proposing in part 507 because they all have in common the goal of ensuring that all food, including animal food, is manufactured under conditions and practices that protect against contamination with undesirable biological, chemical, physical, and radiological agents. At least one organization, Codex, in the context of animal food, articulated the need for a facility to have a prerequisite program, such as CGMPs, before establishing a HACCP program (Ref. 43). FDA's adoption of animal food CGMPs would establish such a prerequisite program for the preventive controls program for animal food under section 418 of the FD&C Act. Such a prerequisite program already exists for human food.

In addition to the risk to animals, the proposed animal food CGMPs address risks to human health from individuals handling animal foods or individuals consuming products from food-producing animals. The human food CGMPs in part 110 are designed to address risks to humans, and the Agency has experience and expertise in the human food CGMPs. Therefore, after considering the animal food CGMP documents from the previously mentioned organizations, and the Agency's CGMP regulations for human food, the Agency tentatively concludes that the human food CGMPs provide an appropriate starting point for the animal food CGMPs. The Agency requests comments on this tentative conclusion. The CGMPs proposed here in subpart B for animal food address the same areas as the current human food CGMPs in part 110 and the proposed revisions that would be incorporated into proposed part 117 (under the proposed rule for preventive controls for human food published (78 FR 3646)) and cover the following areas: Personnel; plant and grounds; sanitary operations; sanitary facilities and controls; equipment and utensils; processes and controls; and warehousing and distribution.

The proposed animal food CGMPs are not identical to the current and proposed human food CGMPs. The proposed animal food CGMPs do not address "cross-contact", which for human foods is related to the inadvertent incorporation of allergens into foods. The Agency is not aware of evidence indicating that foodborne allergens pose a significant health risk to animals, or to humans through handling animal food. In addition, the proposed animal food CGMPs do not include a provision related to raw materials and ingredients, including rework susceptible to contamination with pests, undesirable microorganism, or extraneous materials complying with FDA regulations for natural or unavoidable defects if a manufacturer wishes to use such materials in manufacturing such food. Unlike for human food, there is no agency regulation for natural or unavoidable defects for animal foods at this time. The proposed animal food CGMPs do not include the limitation in the current human food CGMPs (part 110) that food manufacturing areas and equipment used for manufacturing human food must not be used to manufacture nonhuman food grade animal food or inedible products, unless there is no reasonable possibility for contamination of the human food. The Agency does not consider such a limitation necessary for ensuring the safety of animal food, if the animal food is subject to the proposed CGMPs.

While FDA has tentatively concluded that CGMPs similar to those for human food would be appropriate for animal food, the Agency understands that animal food is produced in a wide diversity of facility types, from small portable animal food mixing units that travel from farm to farm, to large facilities that manufacture food for multiple species of livestock and pets. The Agency is also aware that once the animal food is produced, it may be fed to animals in environments and on surfaces that are not clean. However, basic sanitation measures for animal food are important. For example, the 2010 *Salmonella* Enteritidis outbreak in eggs coming from an egg producer and its associated facilities, demonstrated that *Salmonella* Enteritidis, once in the animal food, could contribute to maintaining the infection of the birds and the eggs they produce (Ref. 45). CDC reported over 1,900 human illnesses related to the outbreak, and FDA reported eggs were shipped to 22 states and Mexico by the initial producer identified in Iowa, and to 14 states by a second producer identified in Iowa (Ref. 46). This *Salmonella* contamination resulted in more than 500 million eggs being recalled. This incident alone demonstrates that the lack of control over the areas this rule is proposing to cover under CGMPs (personnel; plant and grounds; sanitary operations; sanitary facilities and controls; equipment and utensils; processes and controls; and warehousing and distribution), can and does lead to the spread of contamination of animal food within a facility. The loss of control in these areas resulted in the spread or recycling of the contamination, and at a very minimum, limited the ability of the producer to eliminate the contamination within the feed mill.

To emphasize the need for required CGMPs in the animal food industry, the following are actual observations from the FDA 483, List of Observations for a feed mill associated with the *Salmonella* in eggs outbreak (Ref. 47). This feed mill supplied animal food to both facilities involved in the outbreak:

"8. On xx/xx/10, the following observations were noted at the ****** Feed Mill located at *****, IA:

Specifically,

- Birds were observed roosting and flying, chicks heard chirping in the storage and milling facility. In addition, nesting material was observed in the feed mill closed mixing system, ingredient storage and truck filling areas.
- Raw ingredient bins and feed sensors accessible from the roof of the facility had rusted holes and feed grain level sensors ajar in the outdoor environment. These include:
- Ingredient storage bin 12 containing slat, had a rusted gap about a ½ inch wide the length of the lid of the roof level covered ingredient bin chute.
- Ingredient storage bin 21 containing ground corn had a hole approximately 3 inches by ½ inch wide at the base of the roof level cover ingredient bin chute.
- At the base of the feed grain level sensor leading into ingredient storage bin 21, containing ground corn, there was an open hole.
- Feed grain level sensor leading into ingredient storage bin 7, containing meat and bone meal, was off to the side with approximately a 2 inch gap. Avian like feces was observed on top to this feed sensor.
- Finished feed tanks 4 and 18 did not have covers on top of the finished feed tank chutes.
- Outdoor whole kernel corn grain bins 4 and 6 observed to have the top side doors/lids open to the environment and pigeons were observed entering and leaving these opening. Birds were also observed sitting/flying around and over openings."

In addition to the previous observations, environmental samples collected from a top floor outlet location and two second floor covers all tested positive for *Salmonella* Enteritidis that the FDA laboratory confirmed as indistinguishable from the outbreak strain. The environmental positives at various levels within the feed mill are noteworthy because they illustrate the importance of overall sanitation within the facility. Without addressing worker hygiene practices, and other sanitary practices detailed in the proposed CGMPs, a situation could arise whereby contamination could be spread throughout the facility by workers, equipment, and pests.

Whether animal food was the source of this *Salmonella* Enteritidis outbreak was never determined, but it is clear that the lack of overall sanitation contributed to contaminated feed and infection in the laying flock. Adherence by this firm to CGMPs for animal food could have been critical in controlling Salmonella contamination of the poultry facility.

As discussed in section II.E, the CDC reported that in a 2006–2007 multi-state outbreak, 79 human cases of salmonellosis were subsequently linked to *Salmonella* Schwarzengrund in dry dog foods that were manufactured by a company in the United States (Ref. 24). The company stopped production at the facility on July 29, 2007, when it was alerted to a possible link between dry pet food produced at the plant and people infected with *Salmonella* Schwarzengrund. The facility immediately recalled the suspected product. The source or cause of the contamination at the facility was not determined, but the company stopped production at the facility, did extensive cleaning, and resumed production at the facility after the cleaning and sampling showed negative *Salmonella* results from environmental and equipment sampling. The company ultimately closed the facility in 2008 when subsequent finish product testing by the facility again revealed *Salmonella* Schwarzengrund (Ref. 24).

The previous examples demonstrate that failure of an animal food facility to control the overall plant production environment, whether the plant manufactures, processes, packs, or holds food for pets or for food-producing animals, can and does result in human disease. In addition, regulations addressing the production of human food obtained from animals do not address the safety or production of animal food being fed to those food-producing animals. The Agency concludes that the previously described situations point to the need for this proposed rule for animal food, including the need for CGMPs.

The Agency realizes that there is a spectrum of animal food producers and production facilities and that the hazards and risks can vary greatly. Therefore the Agency is requesting comment on its thinking that CGMPs similar to those for human food are appropriate for animal food. The Agency is also requesting comment on whether CGMP requirements that would be more appropriate for some types of animal food may not be appropriate for other types, and, if so, how the Agency can or should distinguish between those types during the various stages of animal food processing.

The need for enforceable baseline standards for producing safe animal food was a major consideration in FDA's decision to propose CGMPs as part of its preventive controls regulations. Animal food facilities that are not subject to section 418 of the FD&C Act would be required to meet these baseline practices proposed in these CGMPs to prevent contamination of animal food. Facilities that are already adhering to trade association best practices, international standards described above, AAFCO model GMPs, or State animal feed regulations, may have their own strong quality control programs in place and may already be satisfying the CGMP requirements proposed here. Those firms that do not have such practices in place would have to implement them under this proposed rule, or be subject to enforcement action by FDA.

B. Proposed Current Good Manufacturing Practices (CGMPs) for Animal Food

1. Proposed § 507.14—Personnel

FDA is proposing in § 507.14 to require that personnel in animal food facilities conform to hygienic practices and receive appropriate training to protect against contamination of animal food. Section 507.14(a) would require that employees with an illness or open lesion that could reasonably be a source of contamination of animal food report the condition to their supervisor and refrain from performing activities that could result in contamination of animal food.

This proposed requirement is similar to PAS 222 at 13.5, which requires persons known or suspected to be infected with, or carrying, a disease or illness transmissible through animal feed intended for feeding within the home to be prevented from handling such food and food contract surfaces. Codex animal food CGMPs include a similar provision for all food employees who may be carriers for any disease or illness likely to be transmitted through animal food (Refs. 2 and 44).

Proposed § 507.14(a) would also require that while on duty employees maintain adequate personal cleanliness as appropriate for the activities they are performing. For example, employees would be required to wash their hands before starting work and at any other time when the hands become soiled or contaminated. The Agency is not proposing to require that employees wash their hands after each absence from the work station, as in the human food CGMPs, because in the animal food industry employee responsibilities are not typically limited to work stations. Employees would also need to secure jewelry and other objects such as personal belongings, tools, and writing implements to prevent them from falling into animal food, and store clothing and personal belongings in areas where they will not contaminate animal food. The Agency has received RFR reports of foreign objects such as pieces of a metal tape measure, plastic pieces from a hard hat, stainless steel shavings, and fragments of a soda can that were mixed into the animal food. In most of these reports, animal deaths occurred due to the consumption of the foreign objects in the food (Ref. 48).

For animal food, the Agency is not proposing some of the requirements in the human food CGMPs as proposed part 117. FDA tentatively concludes that certain requirements are necessary for ensuring the safety of animal food across the board, while other precautions may be important for some animal food facilities and not others, depending on the type of animal food handled at the facility, the species for which the animal food is intended, and whether human consumers could come into direct contact with the animal food, among other considerations. For example, the Agency is not proposing specific requirements for: Employees to wear certain types of outer garments; maintenance of gloves; wearing, hair nets, beard covers, etc.; confining certain activities to areas other than where animal food may be exposed or where equipment or utensils are washed; or specifying the foreign substances for which necessary precautions must be taken to protect against contamination of animal food, animal food-contact surfaces, or animal food packaging materials. The animal food proposed rule includes a general provision that would require the establishment to take any other necessary precautions to protect against contamination of animal food, animal food-contacts, or animal food packing materials. This broad provision would allow the individual facility to determine if it needed to use outer garments, hairnets, etc. for the particular animal food being manufactured, processed, packed, or held at that facility. FDA tentatively concludes that this approach is appropriate when considering the diversity of the animal food industry.

Both the PAS 222 and the Codex animal food CGMPs address these areas, requiring personal hygiene for employees and requiring that items such as jewelry be secured. Unlike this proposed rule, the PAS 222 and the Codex animal food CGMPs provide for protective clothing and hair coverings where appropriate (Codex) and fit for the purpose (Refs. 2 and 44).

Proposed § 507.14(b) would recommend that personnel responsible for identifying plant sanitation failures or animal food contamination should have a background of education or experience to provide a level of competency necessary for production of clean and safe animal food. It would also recommend that animal food handlers and supervisors receive appropriate training in proper food handling techniques, food-protection principals, and be informed about the risks of poor personal hygiene and insanitary practices. The PAS 222, the AAFCO Model animal food CGMPs, and the Codex animal food CGMPs all provide for training of personnel in their areas of responsibility. As discussed in section IX.C, FDA is requesting comment on whether to change the recommendations to requirements for education or training in proper food handling techniques and food-protection principles.

FDA is proposing in § 507.14(c) that responsibility for ensuring compliance with all requirements in subpart B be clearly assigned to competent supervisory personnel.

2. Proposed § 507.17—Plant and Grounds

Plant, as defined in proposed § 507.3, means the building or establishment or parts thereof used in connection with the manufacturing, processing, packing, or holding of animal food. FDA is proposing in § 507.17(a) that the area around a plant be maintained so that it does not serve as a source of contamination of animal food.

Methods for adequately maintaining the grounds around a plant include properly storing equipment, removing litter and waste, and cutting weeds and grass within the immediate vicinity of plant buildings and structures. Litter, waste, tall grass, weed, and old equipment around plants can harbor pests which will try to enter the facility and could contaminate animal food and ingredients. Roads, yards, parking lots, and other areas in the vicinity of the plant would be required to be maintained and adequately drained so as not to contribute to contamination of animal food by seepage, foot-borne filth, or providing a breeding place for pests. Water seepage into animal food ingredients and finished products can promote growth of mold which could produce mycotoxins in the animal food. The PAS 222 (p. 4) contains a provision similar to proposed section 507.17(a). It provides the [s]ites to be maintained in good order. Vegetation shall be tended, removed or otherwise managed to address animal food safety hazards. Roads, yards and parking areas shall be drained to prevent standing water and shall be maintained (Ref. 44).

Proposed § 507.17(b) would require that the plant's size, construction and design allow for cleaning, maintenance, and exclusion of pests. Specifically, this proposed section would require that the size of the plant provide sufficient space to place equipment, store materials, and allow precautions to be taken to prevent contamination of animal food inside the plant and in outdoor bulk vessels. It would also require that construction of the plant be such that floors, walls, and ceilings can be kept clean and in good repair; that condensate from fixtures, ducts, and pipes not contaminate animal food; that there be enough space between equipment and walls to permit employees to perform their duties and protect against contaminating animal food; that lighting be adequate, and lighting fixtures, skylights, and other glass suspended over exposed food be of such construction that in case of breakage, glass does not contaminate animal food; that sufficient ventilation be provided to minimize odors and vapors without contaminating animal food; and that where necessary, adequate screening be provided to protect against pests. Proposed § 507.17(b) would also require that the design and construction of buildings and structures allow for separation of operations, for example by location or time, to reduce the potential for contamination of animal food, animal food-contact surfaces, and animal food-packaging material with microorganisms, chemicals, filth, or other extraneous material.

The Codex animal food CGMPs contain similar provisions that state that locations, design and construction of premises should deter pests and restrict access to pests to a minimum. Building and facilities should be designed to allow easy access for cleaning, including access to the inside of relevant equipment. There should be enough space to satisfactorily conduct all process operations and products inspections. Lighting sources should be sufficient to ensure that hygienic conditions are maintained throughout the product and storage areas. There should be protected lighting fixtures. There should be adequate means of ventilation to minimize airborne contamination of animal food from aerosols and condensation droplets (Ref. 2).

3. Proposed § 507.19—Sanitary Operations

Proposed § 507.19(a) would require that buildings, fixtures, and other physical structures be maintained in sufficient sanitary condition and repair to prevent animal food from becoming adulterated. Equipment and utensils would need to be cleaned and sanitized to protect against contamination of animal food, animal food contact surfaces, and animal food packaging materials. Reports of animal food contamination continue to be reported to the Agency due to improper flushing (cleaning) of equipment. In one incident, a vitamin D supplement for a poultry food was carried over to a dog food. The excessive vitamin D levels in the pet food caused toxicity in the animals consuming the food (Ref. 48). In addition, during facility inspections, FDA has identified forklifts, carts and other material handling equipment as sources of cross contamination between raw ingredients and finished products.

The PAS 222 provides for cleaning programs to be established and documented to maintain hygienic conditions. The Codex animal food CGMPs provide that cleaning should remove residues and dirt that may be a source of contamination. Sufficient standard of cleanliness should be employed to ensure that exposure to pests and pathogens is minimized at all stages of processing, storage, and handling of animal food (Ref. 43).

FDA is proposing in § 507.19(b) that cleaning compounds and sanitizing agents must be free from undesirable microorganisms, and that they must be safe and adequate for the conditions of use. Compliance with this requirement could be verified by any effective means, including purchase of these substances under a supplier's guarantee or certification, or examination of these substances for contamination.

In § 507.19(c), the Agency proposes that only certain types of toxic materials, such as cleaning compounds, laboratory testing reagents, and lubrications for equipment, be used or stored in the plant. In addition these compounds must be identified, held, and stored in a manner that protects against contaminating animal food.

Both the PAS 222 and the Codex animal food CGMPs provide for cleaning and sanitizing agents to be stored separately to minimize the risk of contaminating animal food.

Proposed § 507.19(d) would require that effective measures be taken to exclude pests from the manufacturing, processing, packing, and holding areas. The use of insecticides or rodenticides would be permitted only under precautions and restrictions that will protect against the contamination of animal food, animal food-contact surfaces, and animal food-packaging materials. As in the human food context, pests can be vectors for disease through microbial contamination of animal food. The AAFCO, PAS 22, and the Codex CGMP documents all address the need to exclude pests from the facility.

FDA is proposing in § 507.19(e)(1) and (e)(2) that animal food contact surfaces be cleaned as frequently as necessary to protect against contamination of animal food. Cleaning requirements would vary depending, for example, on whether equipment and utensils are used for manufacturing or holding low-moisture animal food, used for wet processing operations, or used in continuous production operations.

Proposed § 507.19(e)(3) would recommend that single-service articles (such as paper cups or paper towels) be stored in appropriate containers. Section 507.19(e)(3) is also proposing that these single-service articles be handled, dispensed, used, and disposed of in a manner that protects against contamination of animal food, animal food-contact surfaces, or animal food-packaging materials. As discussed in section IX.C, FDA is requesting comment on whether to change the recommendations to requirements for the storage of the single-service articles in appropriate containers.

Proposed § 507.19(f) recommends that non-animal food-contact surfaces of equipment used in the operation of the plant be cleaned in a manner and as frequently as necessary to protect against contamination of animal food, animal food-contact surfaces, and animal food-packaging materials. As discussed in section IX.C, FDA also is requesting comment on whether to change proposed § 507.19(f) to require rather than recommend that non-animal food-contact surfaces of equipment used in the operation of a food plant be cleaned in a manner and as frequently as necessary to protect against contamination of animal food, animal food-contact surfaces, and animal food-packaging materials.

Proposed § 507.19(g) would recommend that cleaned and sanitized portable equipment with animal food-contact surfaces be stored in a place and in a way that would protect any animal-food contact surfaces from contamination. As discussed in section IX.C, FDA also is requesting comment on whether to change proposed § 507.19(g) to require rather than recommend that cleaned and sanitized portable equipment with animal food-contact surfaces and utensils be stored in a location and manner that protects animal food-contact surfaces from contamination.

4. Proposed § 507.20—Sanitary Facilities and Controls

In § 507.20(a), the Agency is proposing that the plant's water supply be sufficient for the operations intended and derived from an adequate source. Any water that contacts animal food, animal food-contact surfaces, or animal food-packaging materials would need to be safe and of adequate sanitary quality. For example, steam added to animal food during the pelleting process would be required to be from a water source that is not contaminated with chemicals, such as petroleum, or pesticides. Running water at a suitable temperature and pressure would need to be provided in all areas where required for the processing of animal food, for the cleaning of equipment, utensils, and animal food-packaging materials, or for employee sanitary facilities.

Proposed § 507.20(b) would require that plumbing in the plant be of adequate size and design and adequately installed and maintained to: (1) Carry sufficient quantities of water to required locations throughout the plant; (2) properly convey sewage and liquid disposable waste from the plant; (3) avoid constituting a source of contamination to animal food, water supplies, equipment, or utensils or creating an unsanitary condition; (4) provide adequate floor drainage in all areas where floors are subject to flooding-type cleaning or where normal operations release or discharge water or other liquid waste on the floor; and (5) ensure that there is not backflow from, or cross-connection between piping systems that discharge waste water or sewage, and piping systems that carry water for animal food or animal food manufacturing.

Proposed § 507.20(c) would require that sewage be disposed of through an adequate sewerage system or through other adequate means.

FDA is proposing in § 507.20(d) that each plant provide its employees with adequate, readily accessible toilet facilities, and that the toilet facilities be kept clean and not serve as a potential source of contamination of animal food, animal food contact surfaces, or animal food-packaging materials. Proposed § 507.20(e) would require that each plant provide hand-washing facilities that are adequate, convenient, and furnish running water at a suitable temperature to ensure that an employee's hands are not a source of contamination of animal food, animal food-contact surfaces, or animal food-packaging materials. Proposed § 507.20(f) would require that rubbish be conveyed, stored, and disposed of in such a way that minimizes the development of odors and the potential to attract, harbor, or create a breeding place for pests.

Sanitary facilities and controls are similarly addressed in PAS 222 in sections 5.2 (water supply), 6.2 (containers for waste), 6.3 (waste management and removal), 6.4 (drains and drainage), and 13.2 (personnel hygiene facilities) (Ref. 44). Water supply, cleaning facilities, waste, and drains are also covered in the Codex animal food CGMPs (Ref. 43). Many of the requirements in the proposed CGMPs follow closely to the PAS and CODEX provisions.

5. Proposed § 507.22—Equipment and Utensils

The Agency is proposing specific requirements for equipment and utensils used in animal food facilities. Proposed § 507.22(a)(1), (a)(2), and (a)(4) through (a)(6) would require that plant equipment and utensils be designed and constructed to allow for the cleaning and maintenance necessary to ensure that animal food would not be contaminated with non-food-grade lubricants, fuel, metal fragments, contaminated water such as condensate, or other contaminants. These requirements would reduce the likelihood of hazards in the animal food that could come from equipment components, such as coolant from an electrical motor leaking onto food contact surfaces. Animal food contact surfaces of equipment and utensils used in the plant would need to be made of nontoxic materials and resist corrosion from contact with animal food or cleaning and sanitizing agents. Proposed § 507.22(a)(3) would recommend that equipment be installed and maintained in such a way to facilitate the cleaning of that equipment and the adjacent spaces. As discussed in section IX.C, FDA also is requesting comment on whether to change proposed § 507.22(a)(3) to require rather than recommend that equipment be installed and maintained in such a way to facilitate the cleaning of that equipment and adjacent spaces.

Proposed § 507.22(b) would require that seams on food-contact surfaces be maintained to minimize accumulation of food particles, dirt, and organic matter and thus minimize the opportunity for growth of microorganisms. Proposed § 207.22(c) would require that equipment in the animal food manufacturing or handling area that does not come into contact with animal food be constructed in a way that enables it to be kept in a clean condition. Similarly, proposed § 507.22(d) would require that systems such as holding, conveying, and manufacturing, be of a design that would enable them to be maintained in an appropriate sanitary condition.

In § 507.22(e), the Agency proposes that freezer and cold storage compartments must be fitted with an indicating thermometer or temperature recording device if the freezer or compartment will be used to store animal food cable of supporting growth of microorganisms.

Proposed § 507.22(f) would require the instruments and controls used for measuring, regulating, or recording various attributes such as temperature, pH, and water activity (a_w), be accurate, precise, and adequately maintained. There also would need to be an adequate number of devices for their designated use.

Proposed § 507.22(g) would require that if compressed air or other gases are mechanically introduced into animal food or used to clean animal food-contact surfaces or equipment, the gas would need to be treated in a way that would not lead to contamination of animal food.

The proposed requirements in § 507.22 are similar to recommendations in the equipment sections of the AAFCO and Codex CGMPs that address the design, construction, and maintenance of equipment to prevent contamination of animal food (Refs. 42 and 43).

6. Proposed § 507.25—Processes and Controls

Proposed § 507.25(a) addresses operations in the manufacturing, processing, packing and holding of animal food. It would require plant management to ensure that all such operations are conducted in accordance with adequate sanitation principles. In addition, it would require plant management to ensure that appropriate quality control operations are employed so that animal food-packaging materials are safe and suitable, that overall sanitation of the plant is under the supervision of one or more competent individuals assigned responsibility for this function, and that all reasonable precautions are taken so that production procedures do not contribute to contamination from any source. In multiple animal food recalls, the cause of the problem was determined to be *Salmonella* contamination of the finished product by raw ingredients when plant employees failed to properly separate finished product from raw ingredients. Under the proposed rule, chemical, microbial, or extraneous-material testing procedures would be required where necessary to identify sanitation failures or possible animal food contamination. Further, all animal food that has become contaminated to the extent that it is adulterated would be rejected, or if permissible, treated or processed to eliminate the contamination.

Proposed § 507.25(a) also addresses labeling controls. It would require that containers holding animal food, raw materials, or ingredients be labeled to accurately identify the contents. The Agency considers the correct identification of animal food, raw materials, and ingredients to be an important step in preventing or minimizing inappropriate handling or utilization of the animal food products during their manufacture, processing, packing, or holding. Labeling for finished animal food products would be required to contain the specific information and instructions needed so the food can be safely used for the intended animal species. Properly labeled finished product could prevent, for example, animal food containing micronutrients such as copper or selenium from being fed to animals for which these ingredients could be injurious to health.

FDA's human food CGMPs, on which the Agency is modeling these animal food CGMPs, do not include labeling controls. However, the Agency tentatively concludes that such controls are necessary for animal food, because unlike human food, a finished animal food is often the animal's sole source of nutrition. Animals of different species can be adversely affected by too low or too high levels of certain nutrients in the food. Because of this, it is important that the labeling correctly reflects the contents of the product and provides the necessary information on how to use the product safely for the type of animals being fed.

The AAFCO Model animal food CGMPs include labeling controls. It provides that a label or other unique identifier shall be affixed to, or accompany, feed and/or feed ingredients to maintain identity and facilitate safe and effective use. Labels shall be stored, handled and used in a manner that minimizes errors. Obsolete labels shall be discarded promptly (Ref. 42). The PAS 222 provides that information on content and intended use of animal food products shall be communicated to customers, for example, on a product label. It also requires that procedures be in place detailing the correct labeling of products in accordance with applicable regulations (Ref. 44).

FDA is proposing in § 507.25(b) that raw materials and ingredients be inspected and segregated or otherwise handled as necessary to ensure that they are clean and suitable for processing into animal food and stored under conditions that will protect against contamination and deterioration and that water used for washing, rising, or conveying animal food must be safe and of adequate sanitary quality. If water is reused, it must not increase the level of contamination of animal food. This section would also require that raw materials and ingredients including rework, be held in bulk, or in containers designed and constructed to protect against contamination, and be held at a temperature, relative humidity, and manner that would prevent the animal food from becoming adulterated. Material scheduled for rework would need to be identified as such. In addition, proposed paragraph (b) would require that raw materials and ingredients must either not contain levels of microorganisms that are reasonably likely to cause illness or injury to animals, or be processed or otherwise treated during manufacturing operations so that they no longer contain levels that would cause the product to be adulterated. Raw materials and ingredients susceptible to contamination with aflatoxin or other natural toxins would need to be in compliance with current FDA regulations for any poisonous or deleterious substances before these materials or ingredients are incorporated into finished animal food. Raw materials received frozen, such as raw meat for raw pet food, would need to be kept frozen until use. If thawing is required prior to use, it must be done in a manner that prevents the raw materials and ingredients from becoming adulterated. Raw materials received and stored in bulk form would need to be held in a manner that protects against contamination.

Proposed § 507.25(b)(1)(iv) would recommend that containers and carriers of raw materials be inspected on receipt to ensure that their condition has not contributed to contamination or deterioration of animal food. Visual inspection alone could identify certain physical hazards in incoming raw materials and ingredients and prevent certain contaminated ingredients from being added to animal food. As discussed in section IX.C, FDA also is requesting comment on whether to change proposed § 507.22(b)(1)(iv) to require rather than recommend that containers and carriers of raw materials and ingredients be inspected on receipt to ensure that their condition has not contributed to contamination or deterioration of animal food.

Proposed § 507.25(c) would require that equipment, utensils, and finished animal food containers used in manufacturing operations be maintained in an acceptable condition through appropriate cleaning and sanitizing, as necessary. All animal food manufacturing, processing, packing, and holding would need to be conducted under conditions that minimize the potential for the growth of microorganisms and contamination of animal food. Animal food that can support the rapid growth of undesirable microorganisms would be required to be held at temperatures that will prevent the animal food from becoming adulterated during manufacturing, processing, packing and holding. Measures such as sterilizing, irradiating, pasteurizing, cooking, freezing, refrigerating, controlling pH, or controlling water activity that are taken to destroy or prevent the growth of undesirable microorganisms would need to be adequate under the conditions of manufacturing, handling, and distribution to prevent animal food from being adulterated. Effective measures would also need to be taken to protect against the inclusion of metal or other extraneous material in animal food. Animal food, raw materials, and ingredients that are adulterated would need to be disposed of in a manner that protects against the contamination of other animal food or, if the adulterated animal food is capable of being reconditioned, be reconditioned using an effective method that has been proven to be safe.

Proposed § 507.25(c)(10) would recommend that animal food be protected from contaminants that my drip, drain, or be drawn into the food. Section 507.25(c)(11) is proposing to recommend that when heat blanching is required in the preparation of animal food, be effected by heating the animal food to the required temperature, holding it at this temperature for the required time, and then either rapidly cooling the animal food or passing it to subsequent manufacturing without delay. Proposed paragraph (c)(11) of this section also would recommend that thermophilic growth and contamination in blanchers be minimized by the use of adequate operating temperatures and by periodic cleaning. As discussed in section IX.C, FDA also is requesting comment on whether to change proposed § 507.25(c)(10) and (c)(11) from recommendation to requirements.

7. Proposed § 507.28—Warehousing and Distribution

Proposed § 507.28(a) would require storage and transportation of animal food to be conducted under conditions that will protect against biological, chemical, physical, and radiological contamination of animal food, as well as against deterioration of the animal food and the container. Establishing a process to control warehouse and distribution practices ensures that the inventory is depleted before the products have deteriorated or decomposed to the point where a hazard develops that would require a preventive control measure. Conveyances used to distribute animal food, including trucks or rail cars, would need to be in a condition that would not contaminate animal food. The Agency is concerned about animal food being adulterated due to improper clean out of conveyances. In one reported incident, recycled broken glass was not completely cleaned out of a tractor trailer used to ship a cattle feed resulting in the glass being dispersed throughout the animal food when it was delivered to the farm (Ref. 48). Additional incidents of incomplete truck clean out include urea contamination of cattle feed that resulted in illness and death to the animals that ingested it (Ref. 48). Animal food that is loaded into a conveyance concurrently with materials that could contaminate the food would need to be properly protected, or loaded onto a separate conveyance. Deterioration of the animal food leading to spoilage or loss of nutrient value would need to be prevented, for example by using properly enclosed conveyances with functioning refrigeration units for animal food requiring temperature control, and by using a stock rotation system during storage.

The Codex animal food CGMPs provide that all means of transport should be appropriately cleaned to control and minimize the risk of contamination. Such vehicles should be subject to regular cleaning and sanitizing programs to ensure clean transport conditions and no accumulation of residual material (Ref. 2). The AAFCO Model animal food CGMPs provide that vehicles used to transport animal food be inspected for cleanliness and structural integrity prior to loading and that feed ingredients or other materials or substances that may pose a risk of adulterating feed or ingredients must not be loaded onto the same vehicle unless measures are taken to minimize such risk (Ref. 42).

C. Alternative To Establish Requirements in Place of Guidance in the Proposed Current Good Manufacturing Practices (CGMPs)

1. Overview

In this section, the Agency requests comment on whether non-binding (should) provisions in proposed subpart B of proposed part 507, should be changed to required (must) provision in the final rule.

The Agency believes that all of the proposed CGMP provisions, including the "should" provisions, are science-based and an important part of a modern food safety system. Because these non-binding provisions have been in place for decades for human food in current part 110, they are widely used and commonly accepted in many sectors of the human food industry. Similarly, the animal food industry is familiar with the principles behind these non-binding provisions. In addition, under section 418(o)(3) of the FD&C Act, the procedures, practices, and processes described in the definition of preventive controls may include sanitation procedures for food contact surfaces of utensils and equipment; supervisor, manager, and employee hygiene training; and CGMPs under part 110 (or any successor regulations).

The costs related to a fully mandatory sanitary operations, process, and controls program would be for the additional time that workers spend in compliance with those parts of proposed §§ 507.19 and 507.20 that are changed from "should" to "must." That alternative, when implemented as part of a preventive approach, would impose incremental annual costs to qualified facilities. Those incremental costs have not been estimated due to a lack of data on current compliance with this alternative at those facilities and the incremental work efforts that would be required with these changes. Most non-qualified facilities would have met the requirements by following the requirements for sanitation controls in subpart C. Those that do not have hazards that are reasonably likely to occur or those with sanitation controls that do not fully address the requirements of the sanitary operations, however, would need to review their operations and implement additional procedures.

2. Summary of Alternative To Establish Requirements in Place of Guidance in the Proposed CGMPs

Table 1 identifies each of the potential differences in the CGMPs in proposed part 507 subpart B that would establish requirements (musts) instead of recommendations (shoulds) and either explains the reason for establishing the requirement or, for such differences with longer explanations, refers to the section where the potential requirement is explained.

TABLE 1—ALTERNATIVE TO ESTABLISH REQUIREMENTS IN PLACE OF GUIDANCE IN THE PROPOSED CGMPS

Proposed designation	Alternative to establish a requirement (must) in place of a recommendation (should) (emphasis added)	Basis for requirement
§ 507.14(b) (Education and training).	Personnel responsible for identifying sanitation failures or animal food contamination must have a background of education or experience, or a combination thereof, to provide a level of competency necessary for production of clean and safe animal food. Animal food handlers and supervisors must receive appropriate training in proper food handling techniques and food-protection principles and should be informed of the danger of poor personal hygiene and insanitary practices.	See explanation and questions about whether more detail would be appropriate in section IX.C.3.
§ 507.19(e)(3) (Sanitation of animal food-contact substances).	Single-service articles (such as utensils intended for one-time use, paper cups, and paper towels) must be stored in appropriate containers and must be handled, dispensed, used, and disposed of in a manner that protects against contamination of animal food, animal food-contact surfaces, or animal food-packaging materials.	Failure to properly store such articles could lead to contamination of the articles and then to contamination of animal food if the articles come in contact with the animal food.
§ 507.19(f) (Sanitation of non-food-contact substances).	Non-animal food-contact surfaces of equipment used in the operation of an animal food plant must be cleaned in a manner and as frequently as necessary to protect against contamination of animal food, animal food-contact surfaces, and animal food-packaging materials.	Failure to clean non-animal food-contact surfaces could lead to contamination of animal food-contact surfaces of the equipment and utensils and then to contamination of animal food if the contaminated equipment and utensils come in contact with animal food. For example, cleaning non-animal food-contact surfaces is essential to prevent contamination of animal food from environmental pathogens such as *Salmonella* spp.
§ 507.19(g) (Storage and handling of cleaned portable equipment and utensils).	Cleaned and sanitized portable equipment with animal food-contact surfaces and utensils must be stored in a location and manner that protects animal food-contact surfaces from contamination.	Failure to properly store and handle such equipment and utensils could lead to contamination of the equipment and utensils and then to contamination of animal food if the equipment and utensils come in contact with animal food.
§ 507.22(a)(3) (Equipment and utensils).	All equipment must be installed and maintained in such a way to facilitate the cleaning of the equipment and of all adjacent spaces.	Failure to properly clean equipment and adjacent spaces due to improper installation and maintenance could lead to contamination of the equipment and then contamination of animal food if the equipment comes in contact with the animal food.
§ 507.25(b)(1)(iv) (Processes and controls—raw materials and ingredients).	Containers and carriers of raw materials must be inspected on receipt to ensure that their condition has not contributed to the contamination or deterioration of animal food.	Containers and carriers of raw materials not properly maintained can lead to contamination or deterioration of animal food.
§ 507.25(c)(10) (Manufacturing operations).	Animal food must be protected from contaminants that may drip, drain, or be drawn into the animal food during manufacturing steps such as washing, peeling, trimming, cutting, sorting and inspecting, mashing, dewatering, cooling, shredding, extruding, drying, defatting, and forming.	There are no circumstances where it would not be necessary to provide adequate physical protection of animal food from contaminants that may drip, drain, or be drawn into animal food.
§ 507.25(c)(11) (Manufacturing operations).	Heat blanching, when required in the preparation of animal food, must be effected by heating the animal food to the required temperature, holding it at this temperature for the required time, and then either rapidly cooling the animal food or passing it to subsequent manufacturing without delay.	Properly heating and cooling animal food during blanching is necessary to protect animal food from contamination and would apply in all cases for animal food when heat blanching is required in the preparation.
§ 507.25(c)(11) (Manufacturing operations).	Thermophilic growth and contamination in blanchers must be minimized by the use of adequate operating temperatures and by periodic cleaning.	Adequate operating temperatures and proper cleaning are necessary for controlling growth of thermophilic bacteria and contamination and would apply in all cases for animal food when heat blanching is required in the preparation.

3. Alternative to the Proposed CGMPs To Establish Requirements (Must) in Place of Guidance (Should) for Education and Training

Proposed § 507.14(b), provides guidance that personnel responsible for identifying sanitation failures or animal food contamination should have a background of education or experience, or a combination thereof, to provide a level of competency necessary for production of clean and safe animal food. Proposed § 507.14(b) further recommends that animal food handlers and supervisors receive appropriate training in proper animal food handling techniques and animal food-protection principles and should be informed of the danger of poor personal hygiene and insanitary practices.

As discussed in section II.A.1 of the document for the proposed rule for preventive controls for human food (78 FR 3646), a CGMP Working Group Report identified specific areas that presented an opportunity to modernize the CGMP regulation for human food. One recommendation was to ''require appropriate training for supervisors and workers to ensure that they have the necessary knowledge and expertise in food hygiene, food protection, employee health and personal hygiene to produce safe food products. This training must be delivered in a manner that can be easily understood by the worker. Food processors must maintain a record of this training for each worker'' (Ref. 49). The Agency's analysis of human food recalls also indicates that ineffective employee training was a root cause of 32 percent of CGMP-related recalls in the 1999–2003 analysis (Ref. 50); deficiencies in training were identified as a contributing factor in 24 percent of CGMP-related primary recalls in the 2008–2009 analysis (Ref. 51). While the Agency does not currently have animal food CGMP regulations to enable it to analyze animal food recalls based on CGMP violations, it believes that these trends of recalls in the human food facilities due to ineffective employee training would be found in the animal food industry as well. In addition, as discussed with respect to the proposed definition of preventive controls (see section VIII.B), section 418(o)(3) of the FD&C Act recognizes the importance of both training and CGMPs in preventing hazards from occurring in foods in its definition of preventive controls, which identifies supervisor, manager, and employee hygiene training (section 418(o)(3)(B)) and CGMPs under part 110 (section 418(o)(3)(F)) as some of the procedures, practices, and processes that may be included as preventive controls.

The vast majority of costs related to a mandatory education and training program would be for the time that workers would be training rather than in production. Lacking data on the education and training programs offered by animal food production facilities, FDA used responses to a 2010 survey of human food production facilities to gauge training needs. The Agency estimates that this alternative, when implemented as part of a preventive approach, could impose an annual cost of $1,136 for those facilities with 10 production employees to $18,300 for those with 200 production employees and that do not already comply with this alternative. This would result in an estimated total annual cost of $11.0 million for domestic and foreign animal food facilities (Ref. 52).

The Agency requests comment on how best to revise proposed § 507.14(b) in light of section 418(o)(3) of the FD&C Act and the recommendations of the human food CGMP Working Group with respect to training. Should the Agency replace the proposed recommendations for personnel education and experience with requirements? Doing so would be consistent with the emphasis in section 418(o)(3) of the FD&C Act on the importance of both training and CGMPs in preventing hazards from occurring in animal foods in its definition of preventive controls and with the recommendation in the human food CGMP Working Group Report. If so, what is the appropriate level of specificity? For example, should the Agency simply replace the ''shoulds'' in the proposed § 507.14(b) with ''musts''? This would provide flexibility for each establishment to determine the type and frequency of education and training appropriate for its personnel.

FDA also requests comment on whether more detail would be appropriate, by, for example:

- Specifying that each person engaged in animal food manufacturing, processing, packing, or holding (including temporary and seasonal personnel and supervisors) receive training as appropriate to the person's duties;
- Specifying the frequency of training (e.g., upon hiring and periodically thereafter);
- Specifying that training include the principles of animal food hygiene and animal food safety, including the importance of employee health and personal hygiene, as applied at the facility; and
- Specifying that records document required training of personnel and, if so, specifying minimum requirements for the documentation (e.g., the date of the training, the type of training, and the person(s) trained).

The Agency also requests comment on whether to establish some or all of the potential requirements for education and training in subpart B, subpart C, or both. If the Agency establishes a requirement for education and training in subpart B, that requirement would apply to all persons who manufacture, process, pack, or hold animal food, with the exceptions of persons who would be exempt from subpart B (e.g., under proposed § 507.5(a) and (h), a requirement in subpart B would not apply to farms, or the holding or transportation of one or more raw agricultural commodities as defined in section 201(r) of the FD&C Act). On the other hand, if the Agency establishes a requirement for education and training in subpart C, that requirement would not apply to persons who would be exempt from the requirements of proposed subpart C (e.g., qualified facilities).

X. Proposed Subpart C—Hazard Analysis and Risk-Based Preventive Controls

A. Proposed § 507. 30—Requirement for a Food Safety Plan

1. Requirements of Section 418 of the FD&C Act

Section 418(h) of the FD&C Act requires that the owner, operator, or agent in charge of a facility shall prepare a written plan that documents and describes the procedures used by the facility to comply with the requirements of section 418 of the FD&C Act, including analyzing the hazards under section 418(b) of the FD&C Act and identifying the preventive controls adopted under section 418(c) of the FD&C Act] to address those hazards. Section 418(h) of the FD&C Act also requires such written plan, together with the documentation described in section 418(g) of the FD&C Act, shall be made promptly available to a duly authorized representative of the Secretary upon oral or written request.

2. Proposed § 507.30—Requirement for a Food Safety Plan

Proposed § 507.30(a) would specify that the owner, operator, or agent in charge of a facility must prepare, or have prepared, and implement a written food safety plan. The Agency uses the term ''written food safety plan'' in proposed § 507.30(a) to mean the ''written plan'' referred to in section 418(h) of the FD&C Act. To make clear that the written plan is related to animal food safety rather than to other plans a facility may have (such as quality control plans or food defense plans), the Agency has designated the "written plan" to be a "written food safety plan."

In drafting the proposed requirements for subpart C described in the paragraphs that follow, the Agency uses wording and formatting that is in some cases slightly different from analogous provisions in the proposed rule for preventive controls for human food published (78 FR 3646). Two types of differences are meant to be substantive: Those relating to ready-to-eat food and those relating to food allergens. Both of those concepts are not applicable in the animal food context. In addition, proposed subpart C of proposed part 507 addresses nutrient imbalances, which are relevant to animal food but not, for the most part, to human food. Otherwise, provisions in proposed subpart C of proposed 507 are meant to have the same meaning as the analogous provisions in proposed subpart C of proposed rule for human food.

Proposed § 507.30(a) would require that the plan be written as is expressly required by section 418(h). A written food safety plan is essential for the facility to implement the plan consistently, train its employees, and periodically reanalyze and update the plan. It is also essential to a facility's food safety team, to auditors, and to inspectors. Proposed § 507.30(a) would implement section 418(h) of the FD&C Act. Proposed § 507.30(a) would provide flexibility for the owner, operator, or agent in charge of the facility to either prepare the written food safety plan or have that plan prepared, in whole or in part, on its behalf. In addition, proposed § 507.30 would provide flexibility for facilities in the development of their food safety plans by allowing facilities to group animal food types or production method types if the hazards, control measures, parameters, and required procedures such as monitoring are essentially identical.

Proposed § 507.30(a) would require that the owner, operator, or agent in charge of a facility implement the written food safety plan. Although section 418(h) of the FD&C Act is silent with respect to implementation of the required written plan, other provisions of section 418 address implementation. For example, section 418(c) of the FD&C Act requires, in relevant part, that the owner, operator, or agent in charge of a facility both establish and implement preventive controls (emphasis added). In addition, other provisions of section 418 (e.g., section 418(d) regarding monitoring, section 418(e) regarding corrective actions, and section 418(f) regarding verification) all establish requirements related to the preventive controls required under section 418(c). As discussed later in this section of the document, the written food safety plan would include the hazard analysis required under section 418(b) of the FD&C Act, the preventive controls required under section 418(c) of the FD&C Act, the monitoring procedures required under section 418(d) of the FD&C Act, the corrective action procedures required under section 418(e) of the FD&C Act, the verification procedures required under section 418(f) of the FD&C Act, and the recall plan as authorized by section 418(o)(3)(E) of the FD&C Act. Specific provisions for implementing these sections of the statute would be established throughout proposed subpart C.

3. Proposed § 507.30(b)—Preparation of the Food Safety Plan by a Qualified Individual

Proposed § 507.30(b) would specify the food safety plan must be prepared by (or its preparation overseen by) a qualified individual. (See the discussion in section X.J regarding the qualifications of a qualified individual as would be established in proposed § 507.50(b)). Section 418 of the FD&C Act requires that firms identify and implement preventive controls and that facilities monitor and verify the effectiveness of the preventive controls. A qualified individual must develop the food safety plan in order to ensure the preventive controls are effective. The plan must be designed to identify and to significantly minimize or prevent hazards in order to prevent illness or injury to animals or humans. Designing a plan requires an individual who is knowledgeable in the concepts of preventive controls, the hazards associated with a product and process, the appropriate preventive controls, with associated monitoring and corrective actions for those hazards, and appropriate verification activities for the applicable preventive controls. Such knowledge requires scientific and technical expertise developed through training, experience, or both.

Section 418 of the FD&C Act does not address the qualifications of the individual who would prepare the food safety plan. However, proposed § 507.30(b) is consistent with the Federal regulations for seafood, juice, and meat and poultry (parts 123 and 120 (21 CFR parts 123 and 120) and 9 CFR part 417 respectively). One way to comply with proposed § 507.30(b) could be for a team of individuals (for example, a "HACCP team" or a "food safety team") to develop the food safety plan under the oversight of a qualified individual. Each member of a HACCP or food safety team generally brings specific expertise important in developing the plan. For example, a microbiologist could provide knowledge of microbial hazards, an engineer could establish the critical parameters for delivery of heat treatments, and a maintenance supervisor could identify sources of metal contamination. Proposed § 507.30 would not require that all such members of a food safety team satisfy the requirements in proposed § 507.30(b) for a qualified individual. However, under proposed § 507.30(b), a qualified individual must be responsible for ensuring that all components the food safety plan have been developed, including reviewing all information contained in the food safety plan, thereby verifying the hazard analysis and food safety plan developed by the food safety team.

4. Proposed § 507.30(c)—Contents of a Food Safety Plan

Proposed § 507.30(c)(1) through (c)(6) would require that the contents of a written food safety plan include:

- The hazard analysis as required by § 507.33;
- The preventive controls as required by § 507.36;
- The recall plan as required by § 507.38;
- The procedures, and the frequency with which these procedures will be performed, for monitoring the implementation of the preventive controls as required by § 507.39;
- The corrective action procedures as required by § 507.42; and
- The verification procedures and the frequency with which they will be performed as required by § 507.45.

Section 418(h) requires that the written plan document and describe the procedures used by the facility to comply with the requirements of section 418, "*including* analyzing the hazards under [section 418(b) of the FD&C Act] and identifying the preventive controls adopted under [section 418(c) of the FD&C Act] to address those hazards" (emphasis added.) Although section 418(h) of the FD&C Act explicitly references sections 418(b) and (c), the term "including," indicates that the contents of a food safety plan need not be limited to the provisions of sections 418(b) and (c) of the FD&C Act.

FDA interprets the requirement in section 418(h) of the FD&C Act that the written plan document and describe the procedures used by the facility to comply with the requirements of section

418 of the FD&C Act to mean that the written food safety plan would include all procedures required under section 418 of the FD&C Act. As discussed in sections X.E.4.a, X.F.2, X.G.6, and X.D.2, the proposed rule would require written procedures for monitoring the implementation of the preventive controls (proposed § 507.39); written corrective action procedures (proposed § 507.42); written procedures for some verification activities (proposed § 507.45); and a written recall plan (proposed § 507.38).

FDA interprets the requirement in section 418(h) that the written plan describe the procedures used by the facility to comply with the requirements of section 418, including analyzing the hazards and identifying the preventive controls adopted to address those hazards, to mean that the contents of the food safety plan must include the hazard analysis conducted by the facility and the preventive controls that a facility must establish for hazards that its hazard analysis identifies as reasonably likely to occur, rather than procedures for analyzing the hazards and procedures for identifying the preventive controls. The general requirement in section 418(a) of the act is directed, in relevant part, to evaluating the hazards that could affect animal food manufactured, processed, packed, or held by a facility, and identifying and implementing preventive controls to significantly minimize or prevent the occurrence of such hazards and provide assurances that such animal food is not adulterated under section 402 of the FD&C Act. Review of the evaluation of hazards in the hazard analysis is sufficient to determine the adequacy of the hazard analysis. Written procedures for conducting the hazard analysis are not necessary. Similarly, the preventive controls identified by the facility can be reviewed fully for adequacy without having a separate procedures document.

5. Facility-Based Nature of the Written Food Safety Plan

The overall framework of section 418 of the FD&C Act is directed to a facility rather than, for example, a corporate entity that may have multiple facilities. For example, under section 418(b) of the FD&C Act the owner, operator, or agent in charge of a facility must identify and evaluate known or reasonably foreseeable hazards *that may be associated with the facility* (emphasis added). Thus, proposed § 507.30 establishes a requirement for every animal food facility to have its own written food safety plan.

Federal HACCP regulations for seafood juice, meat and poultry allow the HACCP plan to group food types or production method types if hazards, critical control points, critical limits, and required procedures such as monitoring, are essentially identical (§ 123.6(b)(2), § 120.8(a)(2), and 9 CFR 417.2(b)(2) respectively.) However, these do provide that any required features of the plan that are unique to a specific product or production method be clearly delineated in the plan and observed in practice. This type of grouping would be allowed under proposed § 507.30, and thus would provide flexibility for facilities in the development of their food safety plans.

B. Proposed § 507.33—Hazard Analysis

1. Requirements of Section 418 of the FD&C Act

Section 418(b)(1) of the FD&C Act specifies, in relevant part, that the owner, operator, or agent in charge of a facility shall identify and evaluate known or reasonably foreseeable hazards that may be associated with the facility, including: (1) Biological, chemical, physical, and radiological hazards, natural toxins, pesticides, drug residues, decomposition, parasites, allergens, and unapproved food and color additives; and (2) hazards that occur naturally, or may be unintentionally introduced. Section 418(b)(3) of the FD&C Act specifies, in relevant part, that the owner, operator, or agent in charge of a facility shall develop a written analysis of the hazards.

As discussed in section II.C.2.f, proposed part 507 is not intended to address "hazards that may be intentionally introduced, including by acts of terrorism." Therefore, the Agency would not be implementing section 418(b)(2) of the FD&C Act in this proposed rule.

Section 418(c)(1) of the FD&C Act specifies that the owner, operator, or agent in charge of a facility shall identify and implement preventive controls, including at critical control points, if any, to provide assurances that hazards identified in the hazard analysis conducted under section 418(b)(1) of the FD&C Act will be significantly minimized or prevented. Section 418(c)(3) of the FD&C Act specifies that the food manufactured, processed, packed, or held by such facility will not be adulterated under section 402 of the FD&C Act, or misbranded under section 403(w) of the FD&C Act.

Section 403(w) of the FD&C Act addresses the labeling of major food allergens, as defined in 201(qq) of the FD&C Act. The misbranding provisions in section 403 of the FD&C Act, when read together with other provisions of the Food Allergen Labeling and Consumer Protection Act, appear to be intended for human food. Therefore, this proposed rule does not address section 403(w) misbranding.

Sections 418(c)(1) and (c)(3) of the FD&C Act, which will be discussed more fully in section X.C.2, are relevant to the discussion of proposed § 507.33(a) regarding the purpose of the hazard analysis required by section 418(b) of the FD&C Act.

2. Proposed § 507.33(a)—Hazard Analysis

a. Proposed § 507.33(a)—Requirement to identify and evaluate hazards. Proposed § 507.33(a) would require that the owner, operator, or agent in charge of a facility must identify and evaluate known or reasonably foreseeable hazards, for each type of animal food manufactured, processed, packed, or held at the facility to determine whether there are hazards that are reasonably likely to occur. As discussed more fully in the remainder of this section, proposed § 507.33(a) would implement section 418(b)(1) of the FD&C Act.

In developing the proposed requirement for a hazard analysis, the Agency considered the language of section 418(b)(1) of the FD&C Act describing the hazards that a facility would be required to identify and evaluate, i.e., "known or reasonably foreseeable hazards that may be associated with the facility." The Agency considers the "known or reasonably foreseeable hazards" in section 418(b) of the FD&C Act to be analogous to the "potential hazards" discussed in the NACMCF HACCP guidelines, and the hazards that are required to be identified to determine if they are "hazards that may be reasonably expected to occur at each step" in the Codex HACCP Annex, or "reasonably likely to occur" in Federal HACCP regulations for seafood, juice, and meat and poultry (Refs. 29 and 36).

Proposed § 507.33(a) would establish the requirement to identify and evaluate hazards by conducting a hazard analysis. The specific requirements for the hazard identification are in proposed § 507.33(b) (see section X.B.3) and specific requirements for the hazard evaluation in proposed § 507.33(c) and (d) (see sections X.B.4 and X.B.5.)

Proposed § 507.33(a) would require that the identification and evaluation of hazards be done "for each type of animal food manufactured, processed, packed, or held at the facility." In developing the proposed requirement for a hazard analysis, the Agency considered the language of section 418(b)(1) of the FD&C Act. The purpose of sections 418(b)(1) appears clear, i.e., that the owner, operator, or agent in charge of a facility identify and evaluate known or reasonably foreseeable hazards that may be associated with the food produced by the facility. The known or reasonably foreseeable hazards associated with the facility's food may differ based on the type of food.

The process of identifying and evaluating the hazards that may occur for specific types of animal food handled in a facility provides an efficient means for keeping track of multiple hazards that may occur in a facility that handles several types of animal food. Such a process also provides an efficient means for ensuring that preventive controls are applied to specific animal food products when required. Thus, a facility may need to conduct multiple hazard analyses. For example, a facility that uses an animal protein blend (by-products derived from meat and animal production industries) as an ingredient in the manufacture of food intended for swine, poultry, dogs and cats, would be required by proposed § 507.33 to identify the *Salmonella* serotypes to which swine, poultry, dogs, and cats are each susceptible (e.g., *Salmonella* Choleraesuis in food for swine; *Salmonella* Pullorum, *Salmonella* Gallinarum, or *Salmonella* Enteritidis in food for poultry) along with an evaluation of the adverse health effects each Salmonella serotype would cause in each of the animal species for which the food is intended (e.g., diarrhea, fever, or pneumonia in pigs caused by *Salmonella* Choleraesuis; diarrhea, gasping, or depression in poultry caused by *Salmonella* Pullorum) (Ref. 14). In addition, for the animal protein blend used in the manufacture of food for dogs and cats, a hazard analysis would need to include the hazards reasonably likely to occur related to the health of human handlers (e.g., pet owners) who are likely to come in contact with the finished food. In other words, if a facility manufactures food for multiple animal species, the Agency would consider the animal food intended for each animal species to be a type of animal food under proposed § 507.33(a), each requiring its own hazard identification and evaluation, even if the animal food the facility produces for each animal species consists of the same primary ingredients. As with the example above, the same biological, chemical, physical, or radiological agent in different types of food intended for different animal species may lead to varied adverse health effects in each of the animal species consuming the food.

To give another example, a facility that uses corn as a raw material in the manufacture of animal food intended for lactating dairy cows, beef cattle, swine, and poultry, would determine if aflatoxin is a reasonably foreseeable hazard that is reasonably likely to occur in the corn. An evaluation of the hazard would include the adverse health consequences to humans consuming milk and milk products from the dairy cows (See FDA Compliance Policy Guide (CPG) 683.100, Action Levels for Aflatoxins in Animal Feeds) (Ref. 15). This evaluation is likely to differ from the evaluation of aflatoxin in corn used to manufacture food for beef cattle, swine, and poultry, where higher levels of aflatoxin, to a point, would not be likely to cause illness or injury to the animals that consume the food or to humans consuming food products derived from those animals (Ref. 15). As a result, in evaluating the same hazard, the hazard analysis for the food for dairy cattle would lead to a different conclusion than the hazard analysis for the food for beef cattle, swine, and poultry.

Proposed § 507.33(a) would identify the purpose of the hazard analysis, i.e., to determine whether there are hazards that are reasonably likely to occur in animal food. Although section 418(b)(1) of the FD&C Act does not explicitly identify the purpose of the hazard analysis, the Agency interprets the combined requirements of sections 418(b), (c)(1) and (c)(3) of the FD&C Act to reflect a purpose, i.e., to enable the facility to identify and, where necessary, implement preventive controls to provide assurances that hazards identified in the hazard analysis will be significantly minimized or prevented and the animal food manufactured, processed, packed or held by the facility will not be adulterated under section 402 of the FD&C Act. If, for example, a facility concludes during the hazard analysis that one or more (or even all) reasonably foreseeable hazards are not reasonably likely to occur in the facility, the facility could conclude that there is no need to implement preventive controls for those hazards. The purpose of the hazard analysis identified in proposed § 507.33 is consistent with the purpose identified in the NACMCF HACCP guidelines, the Codex HACCP Annex, and Federal HACCP regulations for seafood, juice, and meat and poultry.

b. *Requirement for the hazard analysis to be written.* Proposed § 507.33(a) would require that the hazard analysis "be written" as required by section 418(b)(3) of the FD&C Act. A written hazard analysis can help the facility organize the scientific basis for the hazard analysis and would be essential to the facility's food safety team, auditors, and inspectors during review and evaluation of the hazard analysis. The facility's food safety team would need to fully understand the nature of the hazards in order to produce safe animal food. For example, although the facility's food safety plan would include corrective action procedures that address problems that can be anticipated, the food safety team would need to identify appropriate corrective actions when there is an unanticipated problem (see, e.g., the discussion of a proposed requirement (proposed § 507.42) for corrective actions when there is an unanticipated problem in section X.F.3). The written hazard analysis would be useful at these times. Having a written hazard analysis available for auditors and for inspectors is essential for assessing the adequacy of the hazard analysis. A written hazard analysis would also be essential during reanalysis and updates of the hazard analysis, as would be required by proposed § 507.45(e) so that the person doing the reanalysis or update has a baseline from which to start. A written hazard analysis would also be useful for training purposes as a tool to make employees aware of food safety hazards that are reasonably likely to occur.

The written hazard analysis would include the justification for whatever conclusion the owner, operator, or agent in charge of a facility reaches, including a conclusion that no hazards are reasonably likely to occur. Thus, proposed § 507.33(a) would not limit the requirement for a written hazard analysis to those circumstances where the owner, operator, or agent in charge of a facility identifies one or more hazards that are reasonably likely to occur. Under proposed § 507.33(a), a written hazard analysis would be required even if the conclusion of the analysis is that there are no hazards reasonably likely to occur.

3. Proposed § 507.33(b)—Hazard Identification

Proposed § 507.33(b) would require that the hazard analysis consider hazards that may occur naturally or may be unintentionally introduced, including:

- Biological hazards, including microbiological hazards such as parasites, environmental pathogens, and other microorganisms of animal or human health significance (proposed § 507.33(b)(1));

- Chemical hazards, including substances such as pesticide and drug residues, natural toxins, decomposition, unapproved food or color additives, and nutrient imbalances (proposed § 507.33(b)(2));
- Physical hazards (proposed § 507.33(b)(3)) ; and
- Radiological hazards (proposed § 507.33(b)(4)).

Proposed § 507.33(b) would implement section 418(b)(1) of the FD&C Act and would establish four groups of hazards (i.e., biological, chemical, physical, and radiological).

Microbiological Hazards

Proposed § 507.33(b)(1) would include microbiological hazards within the category of biological hazards. Examples of microbiological hazards include:

- Parasites (which are required to be considered by section 418(b)(1)(A) of the FD&C Act). A parasite is an organism that lives on or in an organism of another species (often called the host organism) and receives its nutritional requirements from that other species. *Cryptosporidium* spp., *Giardia* intestinalis, and *Toxoplasma* gondii are examples of parasites.
- Environmental pathogens (e.g., *Salmonella* spp.); and
- Other microorganisms of animal or human health significance, including molds (e.g., *Aspergillus* spp., *Penicillium* spp., and *Fusarium* spp.) and bacteria (e.g., *Salmonella* spp., *Clostridium* spp.)

Chemical Hazards

Proposed § 507.33(b)(2) would include substances such as pesticide and drug residues, natural toxins, decomposition, unapproved food or color additives, and nutrient imbalances (all of which except nutrient imbalances, are explicitly required to be considered by section 418(b)(1)(A) of the FD&C Act) within the category of chemical hazards. Pesticide residues may be present in animal food at levels in excess of a tolerance level established by the U.S. Environmental Protection Agency (EPA). Natural toxins such as aflatoxin and gossypol are well recognized as hazards in animal food products such as corn and cottonseed, respectively (Refs. 53 and 54. Residues of natural toxins such as aflatoxin may be present in human food (such as milk) derived from dairy cattle consuming animal food contaminated with the toxin in excess of a tolerance or safe level established and enforced by FDA (Ref. 15). Decomposition of animal food consists of microbial breakdown of the normal food product tissues and the subsequent enzyme-induced chemical changes. These changes are manifested by abnormal odors, taste, texture, color, etc., and can lead to reduced food intake or rejection of the food by the intended animal species, resulting in illness or death. For example, the metabolic activity of *Fusarium* graminearum growing in or on grain and grain products can lead to changes in the levels of grain nutrients such as carbohydrates, proteins, lipids, or vitamins and formation of deoxynivalenol (DON or vomitoxin). DON can cause diarrhea, vomiting and reduced weight gain in animals consuming food contaminated with the toxin. Swine can smell DON and refuse animal food contaminated with the substance (Ref. 55).

Nutrient imbalance hazards can result from excessive levels of a nutrient in animal food leading to toxicity (e.g., copper poisoning in sheep consuming food with excessive levels of copper), or a nutrient deficiency in the food that can compromise the health of animals (e.g., chickens fed riboflavin deficient diets experience curled toe disease) (Refs. 56, 57, 58, and 59). Nutrient imbalances are particularly problematic for animal food, because often one animal food type is the sole source of an animal's diet. A nutrient imbalance hazard in animal food would pose a greater risk to the health of animals fed a sole source diet than animals receiving multiple types of animal food (like humans eat).

Nutrient imbalance hazards can also result from diets containing essential nutrients in inappropriate proportions of essential nutrients. For example, an animal's calcium needs cannot be considered independently of phosphorus. Calcium, an essential mineral, may be adequate in forage (especially legumes) for grazing cattle. Phosphorus, however, can be deficient in the forages, and since calcium and phosphorus work hand in hand for the animal's muscle and metabolic functions, respectively, supplemental phosphorus at an appropriate level would be needed for cattle on forage-based diets. Calcium and phosphorus are also the major mineral constituents of bone. The calcium to phosphorus ratio in the animal food for cattle would need to be maintained in the desired range to prevent negative health effects associated with nutrient imbalance (e.g. rickets in young animals, osteomalacia in adult animals, reduced resistance to disease, overall reduced productivity including reduced food intake, reduced conception rates, or reduced milk production in cattle) (Refs. 60 and 61).

Physical Hazards

Proposed § 507.33(b)(3) would require that the hazard analysis consider physical hazards, which are required to be considered by section 418(b)(1)(A) of the FD&C Act. Examples of physical hazards include pieces of wood, stones, glass, or metal fragments that could inadvertently be introduced into animal food. Physical hazards may be associated with raw materials, especially raw agricultural products. The facility and equipment can also be a source of physical hazards (e.g., pieces of glass from glass container breakage and metal pieces such as nuts and bolts from equipment used during manufacturing/processing).

Radiological Hazards

Proposed § 507.33(b)(4) would require that the hazard analysis consider radiological hazards. Examples of radiological hazards include radionuclides such as radium-226, radium-228, uranium, strontium-90 and iodine-131. Section 418(b)(1)(A) of the FD&C Act requires that radiological hazards be considered, and animal food may be subject to contamination with radiological hazards, e.g., if water used to manufacture the animal food contains a radionuclide.

4. Proposed § 507.33(c)—Hazard Evaluation

Proposed § 507.33(c) would require that the hazard analysis contain an evaluation of the hazards identified in § 507.33(b) of this section to determine whether the hazards are reasonably likely to occur, including an assessment of the severity of the illness or injury if the hazard were to occur. Proposed § 507.33(c) would implement sections 418(b)(1) and (c)(3) of the FD&C Act. Contamination of animal food with biological hazards often leads to immediate or near-term onset of illness or injury (e.g., gastrointestinal illness in humans after handling pet treats contaminated with *Salmonella*). Exposure to some biological hazards may have long-term consequences as well (e.g., human infections with *Salmonella* may lead to reactive arthritis). The health consequence of exposure to some biological hazards can be severe (e.g., acute enteritis that can cause severe abdominal pain, diarrhea or death in horses exposed to *Salmonella* spp. through consumption of contaminated food) (Refs. 62 and 63). Proposed § 507.33(c) would require that such biological hazards be considered to determine whether they are reasonably likely to occur even if the biological hazard occurs infrequently.

Contamination of animal food with chemical hazards may also lead to immediate or near-term obvious onset of illness, e.g., mycotoxins in large doses can be the primary agent causing acute health or production problems such as diarrhea, metritis, mastitis, or reduced conception rates in a dairy herd (Ref. 64). In other instances, the focus of the evaluation for chemical hazards would be directed to their long term effects, such as liver diseases in animals or humans exposed to aflatoxin over long periods (Refs. 65 and 66). Proposed § 507.33(c) would require that such chemical hazards be considered to determine whether they are reasonably likely to occur even if the chemical hazard occurs infrequently.

Physical hazards such as hard and sharp foreign objects that may be present in animal food can pose a health risk to the animals that consume the food. Hard or sharp foreign objects in animal food may cause traumatic injury, including laceration and perforation of tissues of the throat, stomach and intestine (Ref. 67). Although physical hazards may occur infrequently, under proposed § 507.33(c) the potential for severe consequences would require consideration of these physical hazards to determine whether they are reasonably likely to occur. Factors relevant to an evaluation of the severity of illness or injury caused by a physical hazard include the potential size of the object, the nature of the food, and whether the intended animal species or production class is susceptible to the physical hazard (Ref. 68).

Contamination of animal food with radiological hazards generally is evaluated for long-term effects such as the potential for cancer (Ref. 69). A significant radiation dose could be received as a result of consumption of animal food contaminated as a result of an accident at a nuclear power plant or other types of accidents (Ref. 69) (see also 63 FR 43402, August 13, 1998). Foods may contain unsafe levels of radionuclides (Ref. 70). Thus, although radiological hazards occur infrequently, under proposed § 507.33(c) the potential for severe consequences would require consideration of radiological hazards to determine whether they are reasonably likely to occur for a particular food or facility, especially when circumstances arise that could lead to contamination of food with radiological hazards.

The purpose of section 418(b)(1) and (c)(3) of the FD&C Act seems clear, i.e., that the owner, operator, or agent in charge of a facility identify and evaluate known or reasonably foreseeable hazards for the purpose of identifying and implementing preventive controls to provide assurances that identified hazards will be significantly minimized or prevented and that animal food manufactured, processed, packed or held by the facility will not be adulterated under section 402 of the FD&C Act. The process of evaluating animal food hazards to determine which potential hazards require preventive controls must take into account the consequences of exposure (i.e., severity of illness or injury) as well as the probability of occurrence (i.e., frequency) to provide assurances that the animal food manufactured, processed, packed, or held by the facility will not be adulterated under section 402 of the FD&C Act. Proposed § 507.33(c) would implement this statutory direction.

5. Proposed § 507.33(d)—Effect on Finished Food

Proposed § 507.33(d) would require that, in conducting the hazard evaluation, the qualified individual must consider the effect of the following on the safety of the finished animal food, including:

- The formulation of the animal food;
- The condition, function, and design of the facility and equipment;
- Raw materials and ingredients;
- Transportation practices;
- Manufacturing/processing procedures;
- Packaging activities and labeling activities;
- Storage and distribution;
- Intended or reasonably foreseeable use;
- Sanitation, including employee hygiene; and
- Any other relevant factors.

The Agency tentatively concludes that these are factors that a prudent person who manufactures, processes, packs, or holds animal food would consider when evaluating identified hazards to determine whether they are reasonably likely to occur. As the Agency indicated when proposing FDA's HACCP regulation for juice, a prudent processor should consider factors such as these in doing a hazard analysis (63 FR 20450 at 20468, April 24, 1998).

Proposed § 507.33(d)(1) would require that the hazard evaluation consider the formulation of the animal food. The addition of certain ingredients such as acids and preservatives may be critical to the safety of the food, since they may inhibit growth of, or even kill, microorganisms of animal and health significance. This could impact the evaluation of the potential for growth of pathogens in the animal food during manufacturing, processing, packing or holding. A multi-component food may have individual ingredients that on their own do not support growth of undesirable microorganisms, e.g., because of their oil content or salt content that affects a_w, but when these ingredients are combined the finished food may have an a_w that supports microorganism growth. Under proposed § 507.33(d)(1), the interaction of the individual ingredients must be evaluated as part of the formulation of the animal food.

Proposed § 507.33(d)(2) would require that the hazard evaluation consider the condition, function, and design of the facility and equipment. The condition, function, or design of a facility or its equipment could potentially result in the introduction of hazards into animal food. For example, older equipment (e.g., older belt, bucket elevator, or auger conveying equipment) may be more difficult to clean (e.g., with close fitting components or hollow parts) and, thus, provide more opportunities for pathogens to become established in a niche environment than modern equipment designed to address the problem of pathogen proliferation in niche environments. Proposed § 507.33(d)(2) would require that facilities with such equipment consider the impact of the equipment on the potential for a pathogen to be a hazard that is reasonably likely to occur; in those situations, a preventive control such as enhanced sanitation controls may be appropriate, particularly if the equipment is used in production of animal food products that would not undergo further processing to eliminate pathogens prior to consumption. Equipment designed such that there is metal-to-metal contact may generate metal fragments. Proposed § 507.33(d)(2) would require that facilities with such equipment consider the impact of the equipment on the potential for generation of such metal fragments to be a hazard that is reasonably likely to occur; if so, a preventive control such as metal detectors may be appropriate.

Proposed § 507.33(d)(3) would require that the hazard evaluation consider the effect of raw materials and ingredients on the safety of the finished animal food. While there is an overlap between raw materials and ingredients, not all raw materials are ingredients. Before being used in the manufacturing process, raw materials are often altered to be used in different processes. For example, molasses, a thick, dark syrup, is a byproduct of sugar refining that is used as an ingredient in animal food for cattle. Briefly, to make molasses from sugar cane, washed cane stalks are shredded into short pieces and cane juice separated from the stalks by mechanical (pressing through rollers) or solvent (water or lime juice) extraction methods. The juice is then subjected to a series of processes including filtration, vacuum boiling, and centrifugation to clarify the juice, crystallize out, and separate the sugar leaving the thick syrup (molasses). Because the production process transforms sugar cane stalks, the raw materials, into molasses, those raw materials generally would not be viewed as ''ingredients'' of the final product, molasses. Likewise, if a facility that manufactures animal food for cattle mixes molasses with other food products to make the food, the facility would view molasses as an ingredient of its cattle food product, but would not view the sugar cane stalks used to produce molasses as ingredients of its cattle food product. Animal food can become contaminated through the use of contaminated raw materials or ingredients. For example, corn grown under severely hot and dry weather conditions often becomes infected with *Aspergillus* flavus. Under these environmental conditions, this fungus is likely to produce aflatoxins, resulting in aflatoxin contaminated corn. Corn is one of the most frequently used ingredients in animal food, and corn contaminated with aflatoxins can cause illness in animals consuming food made with the corn and in humans consuming milk derived from dairy cattle consuming food made with the contaminated corn (Refs. 71 and 53).

Production and harvesting practices may impact whether raw materials and ingredients contain hazards. For example, machine-harvested forage or hay is more likely to be contaminated with physical hazards than hand-harvested forage or hay, because the machinery often picks up foreign material from the field. For this reason, machine-harvested forage or hay may lead to increased incidence of hardware disease in cattle (e.g., traumatic reticuloperitonitis developing as a result of perforation of the reticulum), which often occurs when animals consume food contaminated with physical hazards. Cattle commonly ingest heavy, sharp foreign objects because they take large mouthfuls of food and do not completely chew food before swallowing. The disease is common when greenchop, silage, and hay are made from fields that contain old rusting fences or baling wire, because these foods are often machine-harvested. The grain ration may also be a source of physical hazards due to accidental addition of metal such as nails, nuts, or bolts during the production process (Ref. 67).

Proposed § 507.33(d)(4) would require that the hazard evaluation consider the effects of transportation practices on the safety of the finished animal food. Animal food can become unsafe as a result of poor transportation practices. For example, failure to adequately control temperature during transportation could make animal food unsafe if the product requires time and temperature controls to ensure safety. Distributing animal food in bulk without adequate protective packaging can make the food susceptible to contamination during transportation, e.g., from pathogens or chemicals present in an inadequately cleaned vehicle or from other inadequately protected foods that are being co-transported and are potential sources of contamination (Ref. 72).

The Sanitary Food Transportation Act of 2005 (SFTA) gives FDA authority to require shippers, carriers by motor vehicle or rail vehicle, receivers, and other persons engaged in the transportation of food to use sanitary transportation practices to ensure that food is not transported under conditions that may render the food adulterated. The Agency published an Advance Notice of Proposed Rulemaking on April 30, 2010 (75 FR 22713), to request data and information on the food transportation industry and its practices and expects to issue a separate proposed rule to implement the SFTA. FDA does not expect a future rulemaking implementing the SFTA to eliminate the need for the owner, operator, or agent in charge of a facility to consider transportation practices when determining whether a hazard is reasonably likely to occur.

Proposed § 507.33(d)(5) would require that the hazard evaluation consider the effects of manufacturing/processing procedures on the safety of finished animal food. For example, hazards may arise from manufacturing/processing operations such as cooling or holding of certain animal food products due to the potential for germination of pathogenic spore forming bacteria such as *Clostridium* spp. and *Bacillus* spp. (which may be present in animal food ingredients) as a cooked product is cooled and reaches a temperature that would promote germination and outgrowth of the spores. Hazards may also arise from animal food manufacturing/processing activities such as acidification due to the potential for bacterial contamination if the acidification is not done correctly. Physical hazards may occur from metal fragments generated during the manufacture of animal food on equipment in which metal (e.g., a blade, saw, or knife) is used to cut products during manufacturing.

Proposed § 507.33(d)(6) would require that the hazard evaluation consider the effects of packaging activities and labeling activities on the safety of finished animal food. For example, the hazards that are reasonably likely to occur would be different depending on whether the animal food product is distributed in bulk form or packaged in bags. Labels on food for livestock would direct the person feeding animals to use the correct food product for the intended animal species. For example, it is well known that feeding food products to sheep that were intended for other ruminant animal species such as cattle can lead to copper toxicity (poisoning); proper labeling would help to guard against sheep being fed animal food products that are unsafe for sheep.

Proposed § 507.33(d)(7) would require that the hazard evaluation consider the effects of storage and distribution on the safety of finished animal food. For example, biological hazards are more likely to be a hazard that is reasonably likely to occur during storage and distribution in animal food products that require refrigerated storage to maintain safety than in shelf-stable foods. Shelf-stable foods are designed such that biological hazards are controlled.

Proposed § 507.33(d)(8) would require that the hazard evaluation consider the intended or reasonably foreseeable use on the safety of finished animal food. For example, gossypol, a natural toxin commonly occurs in cottonseed food products, can cause severe illness in immature ruminants and young pigs, but the older animals can tolerate low levels of the chemical hazard in their diets. Therefore gossypol would be identified as a hazard of concern if it is reasonably likely to occur at low levels in food for immature ruminants and young pigs but less of a concern in food for older ruminants and for mature pigs.

Proposed § 507.33(d)(9) would require that the hazard evaluation consider the effects of sanitation, including employee hygiene, on the safety of finished animal food. Sanitation measures and practices can impact the likelihood of a hazard being introduced into animal food. For example, the frequency with which a production line in a pet food facility is shut down for a complete cleaning can impact the potential for food residues to transfer pathogens from equipment to foods (e.g., pathogens present on raw meat products that could carry over into the next production cycle on a line). Practices directed at worker health and hygiene can reduce the potential for transfer of pathogens such as *Salmonella.* To the extent that these controls are necessary for the safety of the animal food product, they may need to be listed as preventive controls.

Proposed § 507.33(d)(10) would require that the hazard evaluation consider the effect of any other relevant factors that might potentially affect the safety of the finished animal food. For example, an unexpected natural disaster could flood some or all of a facility, creating insanitary conditions and potentially contaminating the facility with harmful microorganisms or chemical residues. Following a natural disaster, environmental contaminants that could be brought into the facility could be hazards reasonably likely to occur in a facility that manufactures, processes, packs, or holds animal food.

Further discussion of the hazard analysis, including comparison to HACCP, can be found in section XII.B of the document for the proposed rule for preventive controls for human food (78 FR 3646).

C. Proposed § 507.36—Preventive Controls for Hazards That Are Reasonably Likely To Occur

1. Requirements of Section 418 of the FD&C Act

Section 418(c)(1) of the FD&C Act, in relevant part, specifies that the owner, operator, or agent in charge of a facility shall identify and implement preventive controls, including at critical control points, if any, to provide assurances that hazards identified in the hazard analysis conducted under section 418(b)(1) of the FD&C Act will be significantly minimized or prevented. Section 418(c)(1)(3) of the FD&C Act, in relevant part, specifies that the food manufactured, processed, packed, or held by such facility will not be adulterated under section 402 of the FD&C Act

Section 418(o)(3) of the FD&C Act defines preventive controls and proposed § 507.3 would include the statutory definition in proposed part 507. Under section 418(o)(3), the procedures, practices, and processes described in the definition of preventive controls may include the following:

- Sanitation procedures for food contact surfaces and utensils and food-contact surfaces of equipment (section 418(o)(3)(A) of the FD&C Act);
- Supervisor, manager, and employee hygiene training (section 418(o)(3)(B) of the FD&C Act);
- An environmental monitoring program to verify the effectiveness of pathogen controls in processes where a food is exposed to a potential contaminant in the environment (section 418(o)(3)(C) of the FD&C Act);
- A recall plan (section 418(o)(3)(E) of the FD&C Act);
- CGMPs under part 110 or any successor regulations (section 418(o)(3)(F) of the FD&C Act); and
- Supplier verification activities that relate to the safety of food (section 418(o)(3)(G) of the FD&C Act).

2. Proposed § 507.36(a)—Requirement To Identify and Implement Preventive Controls for Hazards That Are Reasonably Likely To Occur

Proposed § 507.36(a) would require that the owner, operator, or agent in charge of a facility identify and implement preventive controls, including at critical control points (CCPs), if any, to provide assurances that hazards identified in the hazard analysis as reasonably likely to occur will be significantly minimized or prevented and the animal food manufactured, processed, packed or held by such facility will not be adulterated under section 402 of the FD&C Act.

As discussed in section X.B, proposed § 507.33(a) would require that the owner, operator, or agent in charge of a facility conduct a hazard analysis to identify and evaluate known or reasonably foreseeable hazards for each type of animal food manufactured, processed, packed, or held at the facility to determine whether there are hazards that are "reasonably likely to occur." Under proposed § 507.36(a), a facility that determines through its hazard analysis that there are hazards that are reasonably likely to occur would then be required to identify and implement preventive controls for those hazards. Preventive controls would be required when applicable hazards are identified as reasonably likely to occur. The types of preventive controls implemented would depend on the facility and the animal food it produces. Most hazards would be addressed through process controls and sanitation controls. For any type of preventive control, a facility would have the flexibility to identify and implement preventive controls from among all procedures, practices, and processes available to it that would provide the assurances that would be required by proposed § 507.36(a).

Proposed § 507.36(a) would implement section 418(c) of the FD&C Act and is consistent with the NACMCF HACCP guidelines, the Codex HACCP Annex, and Federal HACCP regulations for juice, seafood, and meat and poultry, although there are some differences between HACCP systems and the preventive control system established by section 418 of the FD&C Act. It differs in part in that preventive controls may be required at points other than at CCPs and critical limits would not be required for all preventive controls. Under proposed § 507.36(a), a processor could address hazards that are reasonably likely to occur through preventive controls that would be applied at CCPs, but doing so would not be the only option available to the facility in all circumstances. In some cases adequate assurances could be achieved via preventive controls implemented through other procedures and practices of a facility, such as its control parameters for the occurrence of nutrient imbalance hazards, which may not have specific CCPs.

Whatever types of preventive controls a facility chooses to apply in its operations, the requirement in proposed § 507.36(a) would be risk-based. Establishing risk-based preventive controls involves consideration of the available scientific data and information related to animal food safety risks. Typically, the hazard evaluation will enable the facility to determine appropriate risk-based preventive controls for the hazard based on the severity of the hazard and the likelihood of its occurrence.

For example, as discussed in section II.F.4 of this document, *Salmonella* spp. is an environmental pathogen that can establish a harborage in the environment such as on a production line used in manufacturing. Once established, *Salmonella* spp. can intermittently contaminate products on the production line. When a hazard analysis identifies *Salmonella* spp. as a hazard that is reasonably likely to occur in an animal food, the facility would establish sanitation controls to prevent *Salmonella* spp. from establishing itself in a harborage site. In addition to such sanitation controls, a facility may consider applying a bactericidal process step (i.e., a process control applied to adequately reduce levels of *Salmonella* spp.) in animal foods that are handled in the home.

3. Proposed § 507.36(b)—Requirement for Written Preventive Controls

Proposed § 507.36(b) would require that preventive controls for hazards identified in the hazard analysis as reasonably likely to occur be written. Proposed § 507.36(b) would implement section 418(h) of the FD&C Act which, as discussed in section X.A.1, requires that the owner, operator, or agent in charge of a facility prepare a written food safety plan that, among other things, identifies the preventive controls within the plan. Written preventive controls are essential for the facility to implement the preventive controls consistently and essential for the facility's food safety team, auditors, and to inspectors. Written preventive controls also would be essential for training purposes and during reanalysis and updates of the preventive controls.

4. Proposed § 507.36(c)—Requirement for Parameters Associated With the Control of Hazards That Are Reasonably Likely To Occur

Proposed § 507.36(c)(1) would require that preventive controls for hazards identified in the hazard analysis as reasonably likely to occur include, as appropriate to the facility and the animal food, parameters associated with the control of the hazard, such as parameters associated with heat processing, irradiating, and refrigerating animal foods. The parameters are those factors that must be controlled to ensure the hazard will be significantly minimized or prevented. The specific parameters required, and how they would be controlled, would depend on the facility and the animal food. For example, for a heat process, parameters such as temperature and time must be controlled. The heating temperature may be controlled through controls on oven temperature (as when heating product in an oven). The heating time may be controlled by the belt speed for the conveyor on a continuous oven. A facility would have flexibility to establish controls on heating temperature and time through these or other mechanisms.

Some preventive controls may not have specific parameters associated with them. For example, preventive controls for metal may include an equipment preventive maintenance program and a metal detector on the packaging line. These programs may not have specific factors that must be controlled to prevent metal contamination. Sanitation procedures may include scrubbing certain pieces of equipment by hand; this may not require the identification of specific parameters.

Proposed § 507.36(c)(2) would require that preventive controls for hazards identified in the hazard analysis as reasonably likely to occur include, as appropriate to the facility and the animal food, the maximum or minimum value, or combination of values, to which any biological, chemical, physical, or radiological parameter must be controlled to significantly minimize or prevent a hazard that is reasonably likely to occur. Some of the preventive controls a facility may implement may be based upon scientific studies or other information that demonstrate the effectiveness of the control measure at specific values of a biological, chemical, physical, or radiological parameter e.g., the application of heat to animal food at a specific time/temperature combination to adequately reduce pathogens. Proposed § 507.36(c) would also require that a facility that establishes such a preventive control specify values of the essential parameters to be applied in implementing the control. Specifying these values would enable the facility to implement them consistently and would facilitate validation of the preventive controls as would be required by proposed § 507.45(a). Proposed § 507.36(c)(1) and (c)(2) would implement section 418(c) of the FD&C Act and are consistent with the NACMCF HACCP guidelines, the Codex HACCP Annex, and Federal regulations for seafood, juice, and meat and poultry, although there are some differences related to the differences between HACCP systems and the preventive control system established by section 418 of the FD&C Act. FSMA does not use the term "critical limit." Critical limits may not be appropriate for preventive controls that are not applied at CCPs. Thus, proposed § 507.36(c)(1) and (c)(2) use a broader term, i.e., parameter, to encompass preventive controls that may or may not apply at CCPs.

5. Proposed § 507.36(d)(1)—Process Controls

Proposed § 507.36(d)(1) would require that preventive controls for hazards identified in the hazard analysis as reasonably likely to occur include process controls that include those procedures, practices, and processes performed on an animal food during manufacturing/processing that are employed to significantly minimize or prevent hazards that are reasonably likely to occur. Process controls do not include those procedures, practices, and processes that are not applied to the animal food itself, e.g., controls of personnel or the environment that may be used to significantly minimize or prevent hazards that are reasonably likely to occur but are not applied to the food itself. Specifying that process controls are employed during manufacturing/processing to significantly minimize or prevent hazards that are reasonably likely to occur would distinguish those controls applied in manufacturing/processing that significantly minimize or prevent hazards (e.g., screening, drying, cooking, and, irradiating) from other types of controls that may be applied in manufacturing/processing to provide the desired product (e.g., controls for product size and shape).

As discussed in section X.C.4 of this document, proposed § 507.36(c)(2) would require that preventive controls for hazards identified in the hazard analysis as reasonably likely to occur include, when applicable, the maximum or minimum value, or combination of values, to which any biological, chemical, physical, or radiological parameter must be controlled. (For process controls in particular, the term "parameter" used in proposed § 507.36(c)(1), and the value associated with the parameter in proposed § 507.36(c)(2), are associated with the term "critical limit" used in HACCP systems.)

For example, a facility that holds shelled corn in bulk storage units for an extended time period until it is sold or mixed into an animal food may identify the potential for growth of aflatoxin-producing molds on the corn as a hazard reasonably likely to occur. As a process control to prevent such molds from growing on the corn during storage, the facility may elect to dry the corn to a specific moisture content (e.g., no more than 15 percent) prior to placing the corn in storage. The process control would be "drying" and the associated parameter would be moisture level, with its maximum value, or limit, being 15 percent.

6. Proposed § 507.36(d)(2)—Sanitation Controls

Proposed § 507.36(d)(2)(i)(A) and (B) would establish two requirements for sanitation controls where necessary to significantly minimize or prevent hazards that are reasonably likely to occur. Proposed § 507.36(d)(2)(i)(A) would require that the owner, operator or agent in charge of the facility implement, where relevant to hazards that are reasonably likely to occur, sanitation controls that would include procedures for the cleanliness of animal food-contact surfaces, including animal food-contact surfaces of utensils and equipment. Examples of such sanitation controls include cleaning and sanitizing procedures (including appropriate frequencies for these procedures, concentrations of cleaning and sanitizing compounds, method of application, and contact time). Such controls can prevent contamination of animal food with microorganisms of animal or human health significance, including environmental pathogens that result from inadequate cleaning of animal food-contact surfaces.

Proposed § 507.36(d)(2)(i)(B) would require that the owner, operator or agent in charge of a facility implement, where relevant to hazards that are reasonably likely to occur, sanitation controls that include procedures for the prevention of cross-contamination from insanitary objects to animal food, animal food packaging material, and other animal food-contact surfaces and from raw product to processed product. Examples of such controls to prevent cross-contamination include procedures for ensuring that personnel do not touch insanitary objects such as waste and waste bins and then animal food, animal food contact surfaces, or animal food packaging material; procedures for protecting animal food packaging material from environmental contamination; procedures for protecting exposed animal food products from contamination from the environment; and procedures for controlling traffic (including traffic of people and traffic of equipment such as forklifts) between the raw and finished sides of the operation. Any time an animal food is exposed to the environment during a manufacturing, processing, packing, or holding activity, there is the potential for the animal food to be contaminated. Appropriate sanitation controls can minimize the presence and transfer of contaminants, including environmental pathogens, to animal food. (See section I.D and I.E of the Appendix to this document for a discussion on the importance of controlling environmental pathogens.) Proposed § 507.36(d)(2)(i)(A) and (B) would implement section 418(c) of the FD&C Act. For a discussion on sanitation controls under HACCP, see section XII.C.7 for the proposed rule for preventive controls for human food (78 FR 3646).

Proposed § 507.36(d)(2)(ii) would require that the owner, operator, or agent in charge of a facility take action to correct, in a timely manner, conditions and practices that are not consistent with the procedures that would be established in proposed § 507.36(d)(2)(i)(A) or (B) or that result in insanitary conditions that could lead to cross-contamination with a hazard.

Proposed § 507.36(d)(2)(iii) would provide that the owner, operator, or agent in charge of a facility is not required to follow the corrective actions that would be established in proposed § 507.42(a) and (b) when the owner, operator, or agent in charge of a facility takes action, in accordance with proposed § 507.36(d)(2)(ii), to correct conditions and practices that are not consistent with the procedures in proposed § 507.36(d)(2)(i) (A) or (B). As discussed in section X.F, proposed § 507.42(a) would require that the owner, operator or agent in charge of a facility establish and implement written corrective action procedures that must be taken if preventive controls are not properly implemented, and outlines specific components that must be included. Proposed § 507.42(b) would require specific actions in the event of an unanticipated problem when a preventive control is not properly implemented and a specific corrective action procedure has not been established or a preventive control is found to be ineffective. For sanitation controls, proposed § 507.36(d)(2)(ii) would require that the owner, operator or agent in charge of a facility take action to correct, in a timely manner, conditions and practices that are not consistent with the established sanitation control practices.

There are many different ways in which conditions and practices for sanitation can deviate from the established procedures. In many instances the actions taken will be the same, regardless of the deviation. The corrective actions will generally involve re-establishing sanitary conditions (e.g., re-cleaning a piece of equipment) and/or retraining personnel to carry out the procedures correctly. In many instances the procedural deviations are not reasonably likely to impact product (e.g., insanitary animal food-contact surfaces are usually detected by a pre-production inspection of the equipment by plant personnel; deviations in cleaning solution strength rarely result in the production of unsafe product if other cleaning and sanitizing procedures were properly carried out). Thus, there is rarely a need to evaluate the impact of the sanitation failure on animal food and to prevent animal food from entering commerce, as would be required by proposed § 507.42(a)(2) and (a)(3). Because the corrective actions that will need to be taken for most sanitation controls are so general, the Agency sees little benefit in requiring a facility to develop written corrective action procedures for the many sanitation deviations that could occur. The Agency does expect the facility to take action to correct conditions and practices as appropriate to the situation as would be required by proposed § 507.36(d)(2)(ii). The requirement in proposed § 507.36(d)(2)(ii) to take action to correct, in a timely manner, sanitation conditions and practices that are not in accordance with procedures is consistent with proposed § 507.42(a)(1), which would require that appropriate action be taken to identify and correct a problem with implementation of a preventive control to reduce the likelihood that the problem will recur.

Proposed § 507.36(d)(2)(iv) would require that all corrective actions taken in accordance with proposed § 507.36(d)(2)(ii) be documented in records that would be subject to verification in accordance with proposed § 507.45(b)(2) and records review in accordance with proposed § 507.45(c)(1)(i) and (c)(2). The records that document corrective actions would be used to verify that appropriate decisions about corrective actions are being made and appropriate corrective actions are being taken.

7. Proposed § 507.36(d)(3)—Recall Plan

Proposed § 507.36(d)(3) would require that preventive controls include, as appropriate, a recall plan as would be required by proposed § 507.38. Proposed § 507.36(d)(3) would incorporate the statutory definition of ''preventive controls'' from section 418(o)(3)(E) of the FD&C Act, which establishes that preventive controls may include a recall plan. The Agency includes the details of the recall plan in proposed § 507.38 and discusses it in section X.D of this document.

8. Proposed § 507.36(d)(4)—Other Controls

Proposed § 507.36(d)(4) would require that preventive controls for hazards identified in the hazard analysis as reasonably likely to occur include any other controls necessary to satisfy the requirements of proposed § 507.36(a), i.e., to significantly minimize or prevent hazards identified in the hazard analysis and to provide assurance that the animal food manufactured, processed, packed or held by such facility will not be adulterated under section 402 of the FD&C Act.

FDA notes that some of the controls listed in section 418(o) of the FD&C Act are not explicitly identified in proposed § 507.36. As discussed in section X.B, the Agency is not interpreting misbranding under section 403(w), major allergens, to apply to animal food. Therefore, the proposed preventive controls for animal food do not include allergen controls. In section X.K, the Agency requests comment on an environmental monitoring program (which section 418(o)(3)(C) of the FD&C Act indicates is one of the procedures, practices, and processes that preventive controls may include, and which section 418(f)(4) of the FD&C Act identifies as a verification activity.) In section X.L, the Agency also requests comment on a supplier approval and verification program as one of the procedures, practices, and processes that preventive controls my include (section 418(o)(3)(G)). In section IX.C, the Agency requests comment on supervisor, manager, and employee hygiene training. There is a full discussion on CGMPs in section IX of this document. Further, as discussed in section IX.A of this document, such controls are traditionally considered to be part of prerequisite programs, essential to effective preventive controls but often not part of them. FDA expects that compliance with those requirements in proposed part 507, subpart B will be sufficient. However, a facility may determine that in some circumstances it would be appropriate to include certain Current Good Manufacturing Practice provisions among their preventive controls (i.e., as "other controls" in proposed § 507.36(d)(4).

9. Proposed § 507.36(e)—Applicability of Monitoring, Corrective Actions, and Verification

Proposed § 507.36(e)(1)(i) through (iii) would specify that, except as provided by proposed § 507.36(e)(2), the preventive controls required under this section would be subject to monitoring as would be required by proposed § 507.39; corrective actions as would be required by proposed § 507.42; and verification as would be required by proposed § 507.45. Proposed § 507.36(e)(1)(i) through (iii) would restate the requirements of proposed §§ 507.39, 507.42, and 507.45 to clearly communicate the applicability of proposed §§ 507.39, 507.42, and 507.45 to the preventive controls that would be required under proposed § 507.36 and would establish no new requirements.

Proposed § 507.36(e)(2) would provide that the recall plan that would be established in proposed § 507.38 would not be subject to the requirements of proposed § 507.36(e)(1). A recall plan would address animal food that had left the facility, whereas the proposed requirements for monitoring, corrective actions, and verification would all be directed at animal food while it remains at the facility. Thus, as proposed, the requirements for monitoring, corrective actions, and verification have limited applicability to a recall plan. However, a "mock recall" (i.e., a simulated recall situation) is a verification activity that could identify problems with a recall plan, enable a facility to correct the problems, and provide reasonable assurance that the recall plan would be effective in removing products from commerce. FDA requests comments on whether to include a requirement for a mock recall as verification activity in the final rule.

D. Proposed § 507.38—Recall Plan for Animal Food With a Hazard That Is Reasonably Likely to Occur

1. Requirements of Section 418 of the FD&C Act

Section 418(c) of the FD&C Act specifies that the owner, operator, or agent in charge of a facility shall identify and implement preventive controls, including at critical control points, if any, to provide assurances that:

- Hazards identified in the hazard analysis conducted under section 418(b)(1) of the FD&C Act will be significantly minimized or prevented (section 418(c)(1) of the FD&C Act); and
- The food manufactured, processed, packed, or held by such facility will not be adulterated under section 402 of the FD&C Act (section 418(c)(3) of the FD&C Act).

Under section 418(o)(3)(D), the procedures, practices, and processes described in the definition of preventive controls may include, in relevant part, a recall plan.

2. Proposed § 507.38—Recall Plan for Animal Food With a Hazard That Is Reasonably Likely to Occur

Proposed § 507.38(a) would require that the owner, operator, or agent in charge of a facility establish a written recall plan for animal food with a hazard that is reasonably likely to occur. Although a recall is different from other preventive controls in that it is carried out after a product is distributed, it shares the purpose of significantly minimizing or preventing hazards, which is accomplished by limiting feeding of the affected animal food. Time is critical during a recall. A written recall plan is essential to minimizing the time needed to accomplish a recall; additional time during which the animal food is on the market can result in additional animal (or human) exposure. Following an existing plan that addresses all necessary elements of a recall helps minimize delay created by uncertainty as to the appropriate actions to take and helps ensure critical actions are not overlooked.

Proposed § 507.38(a) would implement sections 418(c)(1) and (3) of the FD&C Act and 418(o)(3)(E) of the FD&C Act. Recommendations for addressing a recall, applicable to both human food and animal food, can be found in FDA's general guidance on policy, procedures, and industry responsibilities regarding recalls in part 7 (21 CFR part 7), subpart C (§§ 7.40 through 7.59). The guidance advises firms to prepare and maintain a current written contingency plan for use in initiating and effecting a recall (§ 7.59). Section 507.38(a) would require that the owner, operator, or agent in charge of a facility develop a written recall plan and assign responsibility for performing all actions in the plan.

Proposed § 507.38(b) would require that the written recall plan include procedures to perform the following actions:

- Directly notify the direct consignees of the product being recalled and how to return or dispose of the affected product (proposed § 507.38(b)(1));
- Notify the public about any hazard presented by the animal food when appropriate to protect animal or human health (proposed § 507.38(b)(2));
- Conduct effectiveness checks to verify that the recall is carried out (proposed § 507.38(b)(3)); and
- Appropriately dispose of recalled product, e.g., through destroying the product, reprocessing, or diverting to a use that does not present a safety concern (proposed § 507.38(b)(4)).

Procedures that describe the action to be taken would enable a facility to act promptly by following its plan when the facility determines that a recall is warranted rather than developing a plan of action after the need for a recall is identified. Procedures that assign responsibility for taking those steps would save the time needed to make such determinations during a recall and enable the owner, operator, or agent in charge of a facility to clearly communicate such responsibilities to applicable managers or staff so that such managers or staff can take action as soon as the decision to conduct a recall is made.

Directly notifying direct consignees about the recall (proposed § 507.38(b)(1)) is the most effective mechanism to ensure direct consignees know that the product is being recalled and is consistent with FDA's general guidance on recall communications in § 7.49(a). Further, instructing direct consignees how to return or dispose of an affected product minimizes the chance the affected product will be disposed of improperly and allows direct consignees to act quickly. Further, it is consistent with FDA's guidance on the content of recall communications in § 7.49(c)(4). FDA has provided guidance to industry on a model recall letter (Ref. 73). This guidance may be useful in developing procedures for directly notifying direct consignees about the recall and on how to return or dispose of an affected product.

Notification procedures could identify a variety of communication means, including email, telephone, fax, text messaging, and urgent mail delivery. Notification procedures that would establish only a general notification to the public (e.g., through a press release or through information posted on a facility's Web site), without procedures for concurrent contact directly with direct consignees about how to access the general notification, would not satisfy proposed § 507.38(b)(1); a general notification to the public would rely on the chance that the direct consignees would see the information and may not be effective.

Notifying the public about any hazard presented by the animal food when appropriate to protect human or animal health is a common practice (e.g., see FDA's Web site that provides information gathered from press releases and other public notices about recalls of animal food, Animal & Veterinary Recalls & Withdrawals) (Ref. 74). Notifying the public in such circumstances is consistent with the Agency's guidance on a recall strategy that the purpose of a public warning is to alert the public that a product being recalled presents a hazard to human or animal health (§ 7.42(b)). Notifying the public, in addition to direct consignees, may not be necessary to protect the public if, for example, the animal food being recalled was all distributed to animal feeding operations (who were notified as a direct consignee) and not distributed for retail sale. Procedures in the recall plan for notifying the public could include model press releases and procedures for disseminating information to the public though press releases or other means, such as by information posted on the facility's Web site or provided to end users of the animal food using social media. FDA has provided guidance to industry with a model press release for the presence of *Salmonella* in pet food and pet treats (Ref. 75).

An effectiveness check is a procedure designed to verify that all notified consignees have received notification about the recall and have taken appropriate action; procedures to conduct effectiveness checks would be consistent with FDA's guidance on a recall strategy in § 7.42(c)(3). Procedures to conduct an effectiveness check could expand on the procedures used to directly contact consignees about the recall, e.g., to include forms for consignees to provide information about the amount of recalled product on hand, to include information on follow up contacts via phone or email, or to include personal visits to consignees by sales representatives. FDA has provided guidance to industry on conducting effectiveness checks (Ref. 73). This guidance includes a model effectiveness check letter, a model effectiveness check response form that could be sent to a consignee, and a model questionnaire to be used during effectiveness checks conducted by telephone or by personal visit.

A facility that receives recalled product from its customers must appropriately dispose of the product, e.g., through reprocessing, reworking, diverting to a use that does not present a safety concern, or by destroying the product. These types of disposition actions are similar to the disposition actions that a facility would consider as a corrective action as a result of a problem that is discovered before the product leaves the facility (see, e.g., the discussion of corrective actions in the final rule to establish FDA's HACCP regulation for seafood; 60 FR 65095 at 65127). Procedures for disposition of a product can help the facility ensure that disposition of recalled product will be appropriate and will not present a risk to animals. Implementation of such procedures is part of determining whether a recall can be considered terminated. Thus, having procedures in place can result in more efficient completion of a recall. Under § 7.55, appropriate disposition of recalled product is a consideration in determining whether a recall is terminated.

FDA requests comment on whether the procedures to be included in the recall plan (i.e., to directly notify consignees, to notify the public, to conduct effectiveness checks, and to appropriately dispose of recalled product) are appropriate for all types of facilities or if they should be modified for certain facilities.

FDA requests comment on whether the Agency should require a recall plan to include procedures and assignments of responsibility for notifying FDA of recalls subject to the plan. Notifying FDA could enhance the effectiveness of a recall by allowing FDA to take appropriate steps to minimize the risk of illness or injury related to recalled products. As discussed in section II.E of this document, notifying FDA of a reportable food (including animal food) is required by section 417 of the FD&C Act. Reportable food reports include information about whether a reportable food is being recalled. Thus, in some cases, reporting a recall to FDA could be accomplished by submitting a reportable food report required under section 417. In other cases, facilities could notify the local FDA district office of the recall.

E. Proposed § 507.39—Monitoring

1. Requirements of Section 418 of the FD&C Act

Section 418(a) of the FD&C Act specifies that the owner, operator, or agent in charge of a facility shall monitor the performance of the preventive controls. Section 418(d) of the FD&C Act specifies that the owner, operator, or agent in charge of a facility shall monitor the effectiveness of the preventive controls implemented under section 418(c) of the FD&C Act to provide assurances that the outcomes described in section 418(c) shall be achieved. The outcomes relevant to this proposal are those that provide assurances that hazards identified in the hazard analysis will be significantly minimized or prevented and that food manufactured, processed, packed or held by a facility will not be adulterated under section 402 of the FD&C Act.

Section 418(g) of the FD&C Act requires, in relevant part, that the owner, operator, or agent in charge of a facility maintain records documenting the monitoring of the preventive controls implemented under section 418(c) of the FD&C Act.

Section 418(h) of the FD&C Act requires, in relevant part, that the owner, operator, or agent in charge of a facility prepare a written plan that documents and describes the procedures used by the facility to comply with the requirements of section 418 of the FD&C Act.

2. Monitoring, Verification, and Their Relationship

Proposed § 504.3 would define "monitor" to mean "to conduct a planned sequence of observations or measurements to assess whether a process, point, or procedure is under control and to produce an accurate record for use in verification." Monitoring is essential to managing food safety because it facilitates tracking of the operation (i.e., the "process, point, or procedure" that is being controlled). This provides ongoing information about whether the process, point, or procedure is under control (i.e., operating according to plan), and can provide information about shifts away from control. If monitoring indicates that there is a trend towards loss of control, a facility can take action to bring the process back into control before a deviation from a maximum or minimum value (critical limit) occurs. For example, if the minimum oven temperature needed to ensure pathogen elimination during baking of a particular size pet treat is 300 °F for a specific time and the procedure for baking pet treats calls for an operating temperature of 375 °F, monitoring would detect that the temperature in the oven was dropping and enable the facility to identify and fix the problem with the temperature before the temperature drops to 300 °F. In addition, monitoring is used to determine when a deviation occurs at a critical control point (i.e., exceeding or not meeting a critical limit), indicating there is loss of control. In the previous example, there would be loss of control if the temperature drops to 299 °F. When a deviation occurs, an appropriate corrective action must be taken, e.g., stop the baking process until the temperature in the oven can be maintained above 300 °F and reprocess the pet treats that were not baked at the appropriate temperature. Also, monitoring provides written documentation for use in verification. For example, if the facility monitors the temperature of the oven continuously, using a temperature recording device, the output of the temperature recording device is available during the verification activity of review of records. Under this approach, monitoring is directed to evaluating implementation of the preventive controls, and the written documentation of the monitoring is then used in verification.

Proposed § 507.3 would define "verification" to mean those "activities, other than monitoring, that establish the validity of the food safety plan and that the system is operating according to the plan." One aspect of verification, as proposed, is the initial validation of a food safety plan to determine that the plan is scientifically and technically sound, that all hazards have been identified, and that if the food safety plan is properly implemented these hazards will be effectively controlled. Another aspect of verification is evaluating whether the facility's food safety system is functioning according to the food safety plan. Both of these aspects are directed at the effectiveness of a preventive control; they establish that the preventive control is scientifically valid for controlling the hazard and verify that the preventive control is accomplishing its intended purpose. Examples of verification activities include review of monitoring records and review of records for deviations and corrective actions. The Agency discusses verification activities in more detail during its discussion of proposed § 507.45 (Verification) in section X.G.

Monitoring and verification are closely related; both address the performance of preventive controls, and verification relies in part on monitoring records to establish that preventive controls developed to significantly minimize or prevent hazards are being implemented according to plan. Three provisions of section 418(f) of the FD&C Act (Verification) are particularly relevant when considering the role of monitoring. First, section 418(f)(1) of the FD&C Act requires that the owner, operator, or agent in charge of a facility verify that "the preventive controls implemented . . . are adequate to control the hazards identified . . . " Second, section 418(f)(2) of the FD&C Act requires that the owner, operator, or agent in charge of a facility verify that "the owner, operator, or agent is conducting monitoring . . ." Third, section 418(f)(4) of the FD&C Act requires that the owner, operator, or agent in charge of a facility verify that "the preventive controls implemented . . . are effectively and significantly minimizing or preventing the occurrence of identified hazards . . ."

3. Monitoring the Performance of Preventive Controls

Section 418(a) requires monitoring the "performance" of preventive controls whereas section 418(d) requires monitoring their "effectiveness." The Agency tentatively concludes that the language of section 418 regarding monitoring is ambiguous and that it would be appropriate to require monitoring of the performance of preventive controls. "Performance" means "the execution or accomplishment of an action, operation, or process undertaken or ordered" (Shorter Oxford English Dictionary, Fifth Ed. (2002), p. 2157) and is consistent with use of "monitoring" in traditional HACCP. Monitoring the performance of preventive controls would be undertaken to determine whether a facility is implementing its preventive controls and would generate records that would be used to verify implementation of the controls. For example, monitoring performance could include visual observation and measurements of temperature, time, pH, and moisture level. In contrast, "effectiveness" refers to the quality of "having an effect or result" (Shorter Oxford English Dictionary, Fifth Ed. (2002), p. 794) and is not consistent with use of the term "monitoring in traditional HACCP. The term "verification," not "monitoring" is used to refer to effectiveness in traditional HACCP systems. Monitoring the effectiveness of preventive controls would evaluate whether the preventive controls were working.

Requiring monitoring of the effectiveness of the preventive controls would be redundant with required verification activities. Section 418(f) requires verification that the preventive controls are "effectively and significantly minimizing the occurrence of the identified hazards . . ." The activities necessary for such verification are the same as would be required for monitoring the effectiveness of the preventive controls. Requiring monitoring of effectiveness rather than performance of the preventive controls would create a significant gap in the preventive controls system. In contrast, monitoring the performance of preventive controls would provide evidence that the preventive controls established to control the identified hazards are implemented appropriately and thereby are effectively and significantly minimizing or preventing hazards.

Section 418(n)(5) of the FD&C Act directs the Secretary, in issuing these regulations, to review hazard analysis and preventive control programs in existence to ensure that this regulation is consistent to the extent practicable with applicable domestic and internationally-recognized standards in existence. Requiring monitoring of the performance of preventive controls is consistent with applicable domestic and internationally recognized standards.

Therefore, the Agency tentatively concludes that this interpretation is reasonable and proposes to adopt it in the proposed requirements implementing section 418(d) of the FD&C Act. The Agency requests comment on this interpretation.

4. Proposed § 507.39—Monitoring

a. Proposed § 507.39(a)—Requirement for written procedures for monitoring. Proposed § 507.39(a) would require that the owner, operator, or agent in charge of a facility establish and implement written procedures, including the frequency with which they are to be performed, for monitoring the preventive controls. Proposed § 507.39(a) would implement section 418(d) and (h) of the FD&C Act.

Proposed § 507.39(a) would require that the monitoring procedures be written. Under section 418(d) of the FD&C Act, the owner, operator, or agent in charge of a facility must monitor the effectiveness of the preventive controls implemented under section 418(c) of the FD&C Act. Under section 418(h) of the FD&C Act, the procedures used by the facility to comply with the requirements of section 418 of the FD&C Act must be included in the written plan.

Proposed § 507.39(a) would facilitate tracking the implementation of the preventive controls to provide assurance that they are consistently performed; if monitoring indicates that there is a trend towards loss of control, a facility can take action to bring the process back into control before a preventive control is not properly implemented and potentially unsafe product is produced. Further, if monitoring is conducted with sufficient frequency to ensure preventive controls are consistently performed, it will detect if a preventive control is not properly implemented (e.g., if the temperature of an oven falls below the temperature needed to ensure safety), indicating loss of control and signaling the need for an appropriate corrective action. Finally, the proposed monitoring requirement would result in written documentation for use in verification.

To assist the animal food industry in developing their food safety plan, the Agency, in proposed § 507.39(a)(1) through (a)(6), lists the monitoring procedures that it tentatively considers to be the minimum information needed to provide assurances that the outcomes described in proposed § 507.36, ''Preventive controls for hazards that are reasonably likely to occur,'' are achieved. The owner, operator, or agent in charge of the facility, in their written monitoring procedures would need to include the preventive controls that will be monitored. The procedures would also need to include who will perform the monitoring, how the monitoring will be performed, what parameter will be measured if applicable, the frequency of monitoring, and any additional information needed to endure proper monitoring of the preventive controls.

b. Proposed § 507.39(b)—Frequency of monitoring. Proposed § 507.39(b) would require that the owner, operator, or agent in charge of a facility monitor the preventive controls with sufficient frequency to provide assurance that they are consistently performed. Proposed § 507.39(b) does not specify a single monitoring frequency applicable to all facilities and processes. Rather, it requires monitoring with ''sufficient frequency'' to assure that the preventive controls are consistently performed. Proposed § 507.39(b) would implement section 418(d) of the FD&C Act and is consistent with the NACMCF HACCP guidelines and the Codex HACCP Annex.

Continuous monitoring is possible with many types of physical and chemical parameters. For example, the temperature and time for many thermal processes can be recorded continuously on temperature recording charts. If the temperature falls below the scheduled temperature or the time is insufficient, as recorded on the chart, the affected product can be retained and evaluated to determine the appropriate disposition. Examples of other parameters that can be monitored continuously include pressure, flow rate, and pH.

Continuous monitoring may not be possible, or even necessary, in all cases. For example, it may not be practical to continuously monitor the size of particles in a food to ensure they do not exceed the maximum dimensions that are required to ensure a process such as cooking, cooling, or acidification can be properly implemented. If monitoring is not continuous, it may be difficult to ensure that the preventive controls are consistently implemented and a problem has not occurred. Thus, according to NACMCF, the frequency of non-continuous monitoring must be sufficient to ensure that a CCP (or, in the case of this proposed rule, a preventive control) is under control (Ref. 31). The Codex HACCP Annex also notes that, if monitoring is not continuous, then the amount or frequency of monitoring must be sufficient to guarantee the CCP is in control (Ref. 36). The frequency of non-continuous monitoring would depend on factors such as the proximity of operating conditions to the conditions needed to ensure safety and the variability of the process. For example, if the temperature needed to ensure safety of baked pet treats is 300 °F, non-continuous monitoring would need to be more frequent when an oven for baking pet treats is operated at 350 °F than when the oven is operated at 400 °F. As another example, if temperatures vary by 30 °F during processing, monitoring would need to be more frequent than if the variation is only 10–15 degrees.

c. Proposed § 507.39(c)—Requirement for records. Proposed § 507.39(c) would require that all monitoring of preventive controls in accordance with proposed § 507.39 be documented in records that are subject to verification in accordance with § 507.45(b)(1) and records review in accordance with 507.45(c)(1)(i) and (c)(2). Proposed § 507.39(c) would implement section 418(g) of the FD&C Act and is consistent with the NACMCF HACCP guidelines, the Codex HACCP Annex, and Federal HACCP regulations for seafood, juice, and meat and poultry. Further discussion monitoring under HACCP systems can be found in section XII.E of the proposed rule for preventive controls for human food (78 FR 3646).

The monitoring records would be used to verify that the preventive controls are adequate, as would be required by proposed § 507.45(a), and to verify that the preventive controls are effectively and significantly minimizing or preventing the hazards that are reasonably likely to occur, as would be required by proposed § 507.45(d).

Together, proposed §§ 507.39(a), (b), and (c) and 507.45(a), (b), and (d) would establish a system that would provide assurance that hazards identified in the hazard analysis conducted under section 418(b)(1) of the FD&C Act will be significantly minimized or prevented and that food manufactured, processed, packed or held by such facility will not be adulterated under section 402 of the FD&C Act.

F. Proposed § 507.42—Corrective Actions

1. Requirements of Section 418 of the FD&C Act

Section 418(h) of the FD&C Act, in relevant part, specifies that the owner, operator, or agent in charge of a facility shall prepare a written plan that documents and describes the procedures used by the facility to comply with the requirements of section 418 of the FD&C Act. Section 418(e) specifies that the owner, operator, or agent in charge of a facility shall establish procedures to ensure that, if the preventive controls implemented under section 418(c) of the FD&C Act are not properly implemented or are found to be ineffective:

- Appropriate action is taken to reduce the likelihood of recurrence of the implementation failure (section 418(e)(1) of the FD&C Act);
- All affected food is evaluated for safety (section 418(e)(2) of the FD&C Act); and
- All affected food is prevented from entering into commerce if the owner, operator or agent in charge of such facility cannot ensure that the affected food is not adulterated under section 402 of the FD&C Act (section 418(e)(3) of the FD&C Act).

Section 418(f)(4) of the FD&C Act requires, in relevant part, that the owner, operator, or agent in charge of a facility verify that the preventive controls implemented under section 418(c) of the FD&C Act are effectively and significantly minimizing or preventing the occurrence of identified hazards.

2. Proposed § 507.42(a)—Corrective Action Procedures

Proposed § 507.42(a) would require that the owner, operator, or agent in charge of a facility establish and implement written corrective action procedures that must be taken if preventive controls are not properly implemented. Having written procedures in place would enable facilities to act quickly and appropriately when preventive controls are not properly implemented, e.g., when a parameter associated with heat processing exceeds a maximum value or falls below a minimum value. Proposed § 507.42(a) would implement section 418(e) of the FD&C Act. A discussion on the use of corrective actions in HACCP can be found in section XII.F.2 of the proposed rule for preventive controls for human food (78 FR 3646). As discussed in section X.C.4, the proposed rule would establish requirements for preventive controls (which may be at critical control points), and proposed § 507.36(c)(2) would require that the preventive controls include, as appropriate to the facility and the animal food, the maximum or minimum value, or combination of values, to which any physical, biological, radiological, or chemical parameter must be controlled to significantly minimize or prevent a hazard that is reasonably likely to occur. For example, if a parameter associated with heat processing falls below a minimum value, corrective action would be triggered.

The benefits from identifying corrective action procedures in advance of the need to actually take corrective action largely derive from having the procedures in written form. Written corrective action procedures would be essential to the facility's animal food safety team, to auditors, and to inspectors. The facility's animal food safety team will be responsible for ensuring that appropriate corrective actions are taken if preventive controls are not properly implemented. Having access to appropriate, written corrective action procedures determined in advance of the need for such action can ensure that correct and complete actions are taken in a timely fashion without the need for the team to meet and decide on the appropriate action. Having written corrective action procedures available for auditors and for inspectors is essential for them to assess the adequacy of the animal food safety plan; the procedures a facility will use to address implementation failures are essential to the production of safe food, and without them a complete assessment cannot be made. Written corrective action procedures also would be useful for training purposes, so that employees who would need to implement the corrective action procedures will be prepared for what they would need to do.

Proposed § 507.42(a) would implement section 418(e) of the FD&C Act (i.e., that the owner, operator, or agent in charge of a facility must establish corrective action procedures) and section 418(h) of the FD&C Act (i.e., that the owner, operator, or agent in charge of a facility must prepare a written plan).

Proposed § 507.42(a) would require that corrective action procedures describe the steps to be taken to ensure that:

- Appropriate action is taken to identify and correct a problem with implementation of a preventive control to reduce the likelihood that the problem will recur (proposed § 507.42(a)(1));
- All affected animal food is evaluated for safety (proposed § 507.42(a)(2)); and
- All affected animal food is prevented from entering into commerce, if the owner, operator or agent in charge of such facility cannot ensure that the affected food is not adulterated under section 402 of the FD&C Act (proposed § 507.42(a)(3)).

The hazard analysis and risk-based preventive controls in this proposed rule are designed to identify hazards that are reasonably likely to occur, and to significantly minimize or prevent the occurrence of such hazards and provide assurances that such animal food is not adulterated under section 402 of the FD&C Act. However, a preventive controls system accounts for the possibility of implementation and effectiveness problems and includes procedures for addressing those problems and any affected food.

Proposed § 507.42(a) would implement section 418(e)(1) through (e)(3) of the FD&C Act. Section 418(e)(1) of the FD&C Act and is consistent with the NACMCF HACCP guidelines, the Codex HACCP Annex, and Federal HACCP regulations for seafood, juice, and meat and poultry. Section 418(e)(1) and proposed § 507.42(a)(1) explicitly require that action be taken to reduce the likelihood of recurrence of the implementation failure. Although not prescribed by proposed § 507.42(a)(1), reducing the likelihood of recurrence of an implementation failure is best accomplished by identifying the root cause of failure and then taking action to address that root cause. If the root cause is not identified and corrected, it is more likely that the failure will recur. For example, if the temperature of a heat process cannot be maintained, a corrective action to raise the temperature using the controller may correct the problem short-term. However, if the root cause is a lack of boiler capacity to run multiple heating units at the same time, corrective action should address replacing the boiler to increase capacity.

Proposed § 507.42(a)(2) and (a)(3), would require that corrective action procedures include an evaluation of all food affected by a problem and procedures for ensuring that affected food is prevented from entering into commerce if the owner, operator or agent in charge of the facility cannot ensure that the affected food is not adulterated under section 402 of the FD&C Act. Such an evaluation is implicit in the Agency's HACCP regulations for seafood and juice (§§ 123.7(b) and 120.10(a)) in that these sections do not explicitly require that food affected by the problem be evaluated, but do require that steps be taken to ensure that product that is injurious to health or otherwise adulterated does not enter commerce. Although the Agency's HACCP regulations for seafood and juice do not specify the steps that must be described in a corrective action plan, the regulations require that specific steps be taken when a deviation from a critical limit occurs and the processor does not have a corrective action plan that is appropriate for that deviation (§§ 123.7(c) and 120.10(b), respectively). Under the seafood and juice HACCP regulations, required steps include segregating and holding affected product, performing or obtaining a review to determine the acceptability of the affected product for distribution and taking corrective action, when necessary, to ensure that no product enters commerce that is either injurious to health or is otherwise adulterated as a result of the deviation.

3. Proposed § 507.42(b)—Corrective Action in the Event of an Unanticipated Problem

Proposed § 507.42(b)(1) through (b)(3) would require that if a preventive control is not properly implemented and a specific corrective action has not been established, or a preventive control is found to be ineffective, the owner, operator, or agent in charge of a facility take corrective action to identify and correct the problem, evaluate all affected food for safety, and, as necessary, prevent affected food from entering commerce as would be done following the corrective action procedure under proposed § 507.42(a)(3). However, a facility might not anticipate all of the problems that may occur, and a facility may experience an implementation failure for which a corrective action procedure has not been established. Regardless of whether a problem was anticipated and a corrective action procedure was developed in advance, corrective actions to accomplish the steps that would have been included in a corrective action procedure are necessary. Likewise, a facility might determine (e.g., as a verification activity in accordance with proposed § 507.45(c), discussed in section X.G of this document), that a preventive control is ineffective. For example, detecting a pathogen in pet food may signal that preventive controls for that pathogen are ineffective. As in the case of an unanticipated implementation failure of a preventive control, corrective actions would be necessary if a preventive control is found to be ineffective.

Proposed § 507.42(b)(4) would require that the owner, operator, or agent in charge of a facility reanalyze the food safety plan in accordance with proposed § 507.45(e) to determine whether modification of the food safety plan is required if a preventive control is not properly implemented and a specific corrective action has not been established, or if a preventive control is found to be ineffective. (The Agency uses the term ''reanalyze'' when it refers to a reassessment of the validity of a preventive control or the food safety plan to control a hazard.) Under proposed § 507.45(a), the verification required by section 418(f) of the FD&C Act would include validation of the food safety plan, referring to whether it is effectively controlling the hazards or ''working correctly.'' See section X.G of this document for a discussion of proposed requirements for verification (including validation and reanalysis) under section 418(f) of the FD&C Act. Proposed § 507.42(b)(4) would apply to unanticipated food safety problems, and the unanticipated nature of the problems is relevant to the reanalysis of the food safety plan. If the owner, operator, or agent in charge of a facility has assessed its procedures, practices, and processed and has not identified a specific failure as a foreseeable occurrence, the owner, operator, or agent in charge must assess whether the problem is simply an implementation failure that could be expected to occur in the normal course of manufacturing, processing, packing or holding the food, or the result of a system-wide problem that is not being properly addressed by the plan (e.g., ineffective preventive controls.) If the problem is simply an implementation failure, and such a failure is now a foreseeable circumstance, reanalysis of the food safety plan would be necessary to determine whether a corrective action procedure should be established for that foreseeable failure. Likewise, if the problem is the result of a system-wide problem that is not being properly addressed by the plan (or is otherwise a result of ineffective preventive controls), reanalysis of the food safety plan would be necessary to identify effective preventive controls. Either way, reanalyzing the food safety plan and modifying it as necessary would be necessary to reduce the risk of recurrence of the problem. Proposed § 507.42(b)(4) is consistent with the NACMCF HACCP guidelines, the Codex HACCP Annex, and Federal HACCP regulations for seafood, juice, and meat and poultry.

4. Proposed § 507.42(c)—Documentation

Proposed § 507.42(c) would require that all corrective actions taken in accordance with this section be documented in records that are subject to verification in accordance with § 507.45(b)(2) and records review in accordance with § 507.45(c)(1)(i) and (c)(2). The records that document corrective actions would be used to verify that appropriate decisions about corrective actions are being made and appropriate corrective actions are being taken.

G. Proposed § 507.45—Verification

1. Requirements of Section 418 of the FD&C Act

Section 418(f) of the FD&C Act requires that the owner, operator, or agent in charge of a facility verify that:

- The preventive controls implemented under section 418(c) of the FD&C Act are adequate to control the hazards identified under section 418(b) of the FD&C Act (section 418(f)(1) of the FD&C Act);
- The owner, operator, or agent is conducting monitoring in accordance with section 418(d) of the FD&C Act (section 418(f)(2) of the FD&C Act);
- The owner, operator, or agent is making appropriate decisions about corrective actions taken under section 418(e) of the FD&C Act (section 418(f)(3) of the FD&C Act);
- The preventive controls implemented under section 418(c) of the FD&C Act are effectively and significantly minimizing or preventing the occurrence of identified hazards, including through the use of environmental and product testing programs and other appropriate means (section 418(f)(4) of the FD&C Act); and
- There is documented, periodic reanalysis of the plan under section 418(i) of the FD&C Act to ensure that the plan is still relevant to the raw materials, conditions and processes in the facility, and new and emerging threats (section 418(f)(5) of the FD&C Act).

In addition, section 418(g) of the FD&C Act specifies, in relevant part, that the owner, operator, or agent in charge of a facility shall maintain, for not less than 2 years, records documenting the monitoring of the preventive controls implemented under section 418(c) of the FD&C Act, instances of nonconformance material to food safety, the results of testing and other appropriate means of verification under section 418(f)(4) of the FD&C Act, instances when corrective actions were implemented, and the efficacy of preventive controls and corrective actions.

Further, section 418(i) of the FD&C Act specifies that the owner, operator, or agent in charge of a facility shall conduct a reanalysis under section 418(b) of the FD&C Act (the requirement to identify and evaluate known or reasonably foreseeable hazards) whenever a significant change is made in the activities conducted at a facility operated by such owner, operator, or agent if the change creates a reasonable potential for a new hazard or a significant increase in a previously identified hazard or not less frequently than once every 3 years, whichever is earlier. Such reanalysis shall be completed and additional preventive controls needed to address the hazard identified, if any, shall be implemented before the change in activities at the facility is operative. The owner, operator, or agent shall revise the written plan required under section 418(h) of the FD&C Act if such a significant change is made or document the basis for the conclusion that no additional or revised preventive controls are needed. The Secretary may require a reanalysis under section 418(i) of the FD&C Act to respond to new hazards and developments in scientific understanding, including, as appropriate, results from the Department of Homeland Security biological, chemical, radiological, or other terrorism risk assessment.

2. Proposed Requirements for Validation

a. Proposed § 507.45(a)—Validation that preventive controls are adequate to control the hazard. Proposed § 507.45(a) would require that, except as provided by paragraph (a)(3), the owner, operator, or agent in charge of a facility validate that the preventive controls identified and implemented in accordance with § 507.36 to control the hazards identified in the hazard analysis as reasonably likely to occur are adequate to do so. Proposed § 507.45(a) would implement section 418(f)(1) of the FD&C Act. A discussion on validation and how it is used in HACCP systems can be found in the proposed rule for preventive controls for human food (78 FR 3646).

b. Proposed § 507.45(a)(1)—Validation by a qualified individual prior to implementation and on reanalysis. Proposed § 507.45(a)(1) would require that the validation of the preventive controls be performed (or overseen) by a qualified individual. The preventive controls must be adequate to control the hazards identified in the hazard analysis as reasonably likely to occur. Determining whether specific preventive controls are adequate requires an individual who is knowledgeable in the hazards associated with a product and process and the appropriate preventive controls for those hazards. Such knowledge requires scientific and technical expertise developed through training, experience or both.

Proposed § 507.45(a)(1)(i) would require that validation occur prior to implementation of the food safety plan or, when necessary, during the first six weeks of production. The validation of preventive controls includes collecting and evaluating scientific and technical information (or, when such information is not available or is insufficient, conducting studies), as discussed in the next section of this document. The collected data or information, or the studies, would establish a scientific and technical basis for the preventive controls used, in particular those that involve critical control points. This scientific and technical basis largely must be established prior to producing a product to ensure that the animal food produced using those preventive controls will be safe. However, as a practical matter, the scientific and technical basis for some aspects of a preventive control may require production conditions and, thus, would be established by the collection of data or information during, rather than before, producing a product. For example, ensuring that limits for control parameters can be met during production would be done under production conditions. FDA tentatively concludes that preventive controls that require the collection of data or information, or studies, during production conditions are part of validation, and, thus proposed § 507.45(a)(1)(i) would require that the validation of preventive controls be performed, when necessary, during the first 6 weeks of production. The Agency selected six weeks as a time interval that would be adequate to allow facilities to methodically collect data and information during production, yet would be close to implementation of a preventive control.

FDA requests comment on whether the proposed timeframe for validation should be shorter or longer. Comments should provide the basis for an alternative timeframe.

Proposed § 507.45(a)(1)(ii) would require that the validation of the preventive controls be performed whenever a reanalysis of the food safety plan reveals the need to do so. The circumstances under which a reanalysis would be required are addressed in proposed § 507.45(e)(1). Proposed § 507.45(e)(2) would require that the owner, operator, or agent in charge of a facility complete such reanalysis and implement any additional preventive controls needed to address the hazard identified, if any, before the change in activities at the facility is operative, or, when necessary, during the first 6 weeks of production. All preventive controls established to address a hazard identified as reasonably likely to occur must have a scientific and technical basis; establishing that scientific and technical basis is a validation activity regardless of whether the preventive control is established in the facility's initial food safety plan or as a result of reanalysis of the food safety plan.

c. Proposed § 507.45(a)(2)—Validation based on scientific and technical information. Proposed § 507.45(a)(2) would require that, except as provided by paragraph (a)(3) of this section, the validation of preventive controls include collecting and evaluating scientific and technical information or, when such information is not available or is insufficient, conducting studies to determine whether the preventive controls, when properly implemented, will effectively control the hazards that are reasonably likely to occur.

The scientific and technical information that would be evaluated to determine whether preventive controls effectively control the hazards that are reasonably likely to occur may include scientific publications, government documents, predictive mathematical models and other risk-based models, and technical information from equipment manufacturers, trade associations, and other sources. If the qualified individual conducting the validation relies on sources such as scientific publications, the qualified individual would need to ensure during validation that the conditions used by the facility are consistent with those described in the publication that is being used to support the adequacy of the preventive control measure to control the hazard. For example, if a study demonstrates adequate inactivation of *Salmonella* spp. during the manufacturing of dry dog and cat food, conditions such as ingredient matrix, temperature, and heating time, that were critical to achieving inactivation in the study must be the same when the facility manufactures the dry dog and cat food (or any change in the critical parameters must be such that the same or greater lethality is achieved). Documents published by FDA, such as the Food Code (Ref. 76), the Pasteurized Milk Ordinance (Ref. 77), and the Fish and Fisheries Products Hazards and Controls Guidance (Ref. 78) may provide scientific and technical information useful in establishing the validity of a preventive control measure, such as times and temperatures for heating animal food in which bacterial pathogens may be eliminated, or minimum water activities (a_w), minimum pH values, and minimum temperatures for the elimination of a variety of pathogens.

Predictive mathematical models that describe the growth, survival, or inactivation of microorganisms in foods may provide scientific and technical information useful in determining whether a process would be adequate to reduce microorganisms of public health concern (Refs. 79 and 80). Other risk-based models may examine the impact of a control measure on a hazard and may be useful if appropriately validated for a specific animal food. If the model is for a different food, it may still provide useful validation information that could be supplemented by additional data. For example, there are many mathematical models for thermal resistance of *Salmonella* spp. If a model for the thermal resistance of *Salmonella* spp. is developed for the same type of food as the animal food being produced, and the animal food being produced has the same critical parameters such as pH and a_w that were used in developing the thermal resistance model, then heat processes based on the model would generally be considered validated. If the model is for thermal resistance of *Salmonella* spp. in a type of animal food that is only similar to the animal food being produced, or has different critical parameters than were used in developing the thermal resistance model, it would be necessary to conduct additional thermal resistance studies in the animal food being produced to provide the data needed to show that a heat process adequately reduces *Salmonella* spp. in that animal food and to establish the critical parameters for the process. For example, a model for thermal resistance of *Salmonella* spp. on meat and bone meal may not apply to poultry meal, even though the foods are similar in that both are animal by-products. The extent of such studies would, however, be less than the extent of such studies if there were no data on the heat resistance of *Salmonella* spp. in a similar animal food. For example, if the thermal resistance of *Salmonella* spp. in initial studies with canola meal is similar to that for soybean meal then a thermal resistance study used to develop data for canola meal could investigate fewer times and temperatures, or use fewer replicates, than would be the case in the absence of the information about the thermal resistance of *Salmonella* spp. in soybean meal.

A process validation study would establish the relationship between parameters such as process times and temperatures and other factors and the rate at which pathogens are reduced, and a prevalence study would determine the levels at which pathogens may occur in the raw material, ingredient, or animal food product to establish the cumulative amount of pathogen reduction that would be required to adequately reduce the risk of illness from that pathogen. Such studies are typically published or otherwise broadly disseminated within the scientific community and, when properly designed and carried out, are generally regarded by experts as scientifically definitive with respect to the matters addressed by the study. However, if scientific and technical information is not available or is insufficient to support the adequacy of a preventive control measure to control the hazard, the owner, operator or agent in charge of a facility would need to conduct controlled scientific studies to establish that a preventive control measure is adequate to control the hazard.

Information is available in the literature that can assist in the design of studies to support the adequacy of preventive control measures. For example, NACMCF has published information on ‘‘Parameters for Determining Inoculated Pack/Challenge Study Protocols’’ (Ref. 80). Studies to validate preventive control measures must be conducted by persons with experience and expertise relevant to the product, process and hazard to be controlled. Under proposed § 507.45(a)(1), any studies needed to provide the scientific and technical information to establish the validity of the plan would either be conducted by a qualified individual (as would be defined in proposed § 507.3) or would be overseen by a qualified individual. In other words, the qualified individual need not have the experience and expertise to conduct validation studies, but must have sufficient expertise in risk-based preventive controls to understand the studies and how they support the validity of the preventive controls with respect to the hazard of concern.

d. Proposed § 507.45(a)(3)—Preventive controls for which validation is not required. Proposed § 507.45(a)(3)(i) and (ii) would provide that validation need not address:

- The sanitation controls that would be established in proposed § 507.36(d)(2); and
- The recall plan that would be established in proposed § 507.38.

According to NACMCF, verification involves activities to determine the validity of the HACCP plan and that the system is operating according to the plan (Ref. 29). Thus, validation is a verification activity. The purpose of validation is to provide the scientific and technical basis for ensuring that the preventive controls implemented are adequate to control the hazards identified as reasonably likely to occur. FDA tentatively concludes that validation, i.e., the evaluation of scientific and technical information, is either not an essential activity, is not practical or is not relevant, for the controls identified in proposed § 507.45(a)(3).

As discussed in section X.C.6, proposed § 507.36(d)(2)(i)(A) would require that, where relevant to hazards that are reasonably likely to occur, sanitation controls include procedures for the cleanliness of animal food-contact surfaces, including food-contact surfaces of utensils and equipment. Traditionally, sanitarians employed by the facility, or experts employed by companies that supply cleaning and sanitizing compounds, will establish critical parameters and associated limits for cleaning and sanitation, including the choice and strength of the cleaning and sanitizing chemicals, contact time, and temperature requirements, based on studies conducted by the manufacturers of the products. Antimicrobial solutions applied to animal food processing equipment and utensils to sanitize such objects after they have been washed are included in the definition of ‘‘pesticide chemical’’ and therefore, are subject to regulation by EPA under section 408 of the FD&C Act. Chapter 4 (Additional Considerations for Antimicrobial Products) of EPA’s ‘‘Pesticide Registration Manual’’ (Refs. 81 and 82) outlines EPA’s requirements and recommendations for registration of antimicrobial substances, including testing against a validated protocol to be granted EPA-registered claims for pathogen reduction. Thus, FDA tentatively concludes that this proposed rule should not propose to require validation of the adequacy of the sanitation controls that would be required by proposed § 507.36(d)(2)(i)(A). Monitoring activities to ensure the procedures are followed will provide assurance that the controls are functioning as intended to prevent hazards from insanitary animal food-contact surfaces. The Agency requests comment on this approach.

As discussed in section X.C.6, proposed § 507.36(d)(2)(i)(B) would require that, where relevant to hazards that are reasonably likely to occur, sanitation controls include procedures for the prevention of cross-contamination from insanitary objects and from employees to animal food, animal food packaging material, and other animal food-contact surfaces and from raw product to processed product. As already discussed with respect to proposed § 507.36(d)(2)(i)(A), sanitation controls to prevent cross-contamination can be established by companies that supply cleaning and sanitizing compounds without the need for validation.

As discussed in section X.D.7, a recall plan can significantly minimize or prevent hazards by limiting consumption of affected animal food during a recall. Following an existing plan that addresses all necessary elements of a recall helps minimize delay created by uncertainty as to the appropriate actions to take and helps ensure critical actions are not overlooked. The proposed requirement to validate a preventive control by collecting and evaluating scientific and technical information or by conducting studies simply does not apply to such a plan. Thus, FDA tentatively concludes that this proposed rule should not propose to require validation of the recall plan that would be required by proposed § 507.38.

3. Proposed § 507.45(b)(1)—Verification of Monitoring

Proposed § 507.45(b)(1) would require that the owner, operator, or agent in charge of a facility verify that monitoring is being conducted, as would be required by proposed § 507.39. One example of verification that monitoring is being conducted is a periodic observation of the monitoring activity, e.g., by a supervisor. Another example of such a verification activity is an independent test made by a person other than the person doing the monitoring. For example, if the line operator is verifying the operation of a metal detector by running test pieces through the metal detector every 2 hours to verify it rejects them, a quality assurance technician could periodically run a similar test, e.g., once per shift. Proposed § 507.45(b)(1) does not address the review of monitoring records, which would be required under proposed § 507.45(c)(1)(i) (see the discussion later in this section of the document). Proposed § 507.45(b)(1) would implement section 418(f)(2) of the FD&C Act.

Proposed § 507.45(b)(1) would not specify the verification activities that must be conducted for monitoring. The Agency requests comment on whether proposed § 507.45(b)(1) should do so, and if so, what verification activities should be required.

4. Proposed § 507.45(b)(2)—Verification of Corrective Actions

Proposed § 507.45(b)(2) would require that the owner, operator, or agent in charge of a facility verify that appropriate decisions about corrective actions are being made, as would be required by proposed § 507.42 and by proposed § 507.36(d)(2)(ii). An example of verification that appropriate decisions about corrective actions are being made is observation of the corrective actions being taken, e.g., by a supervisor. Proposed § 507.45(b)(2) would implement section 418(f)(3) of the FD&C Act.

Proposed § 507.45(b)(2) would not specify the verification activities that must be conducted for corrective actions. The Agency requests comment on whether proposed § 507.45(b)(2) should do so, and if so, what verification activities should be required.

5. Proposed § 507.45(b)(3)—Implementation and Effectiveness

Proposed § 507.45(b)(3) would require that the owner, operator, or agent in charge of a facility verify the preventive controls are consistently implemented and are effectively and significantly minimizing or preventing the hazards that are reasonably likely to occur, including the requirements in proposed § 507.45(b)(3) and § 507.45(c), as appropriate to the facility and the animal food. Proposed § 507.45(b)(3) and (c) would implement section 418(f)(4) of the FD&C Act, which requires in relevant part verification by "appropriate means" that the preventive controls "are effectively and significantly minimizing or preventing the occurrence of identified hazards."

a. Proposed § 507.45(b)(4)—Calibration. Proposed § 507.45(b)(4) would require calibration of process monitoring instruments and verification instruments. The combination of monitoring (proposed § 507.39(a)), recordkeeping (proposed § 507.55), and verification (proposed § 507.45(a), (b)(4), and (c)) would establish a system that would provide assurance that hazards identified in the hazard analysis conducted under section 418(b)(1) of the FD&C Act would be significantly minimized or prevented and that animal food manufactured, processed, packed, or held by such facility would not be adulterated under section 402 of the FD&C Act. In many instances, monitoring and verification activities rely on instruments (such as a weigh scale or a thermometer) that must be calibrated. Calibration provides assurance that an instrument is measuring accurately. If these instruments are not properly calibrated, the values they provide may not provide the necessary assurance that hazards will be significantly minimized or prevented. If an instrument is calibrated against a known reference, the reference standard may also need periodic calibration (e.g., the standard reference thermometer used to calibrate a thermometer used in processing equipment will itself also need to be calibrated periodically).

Instrument calibration is performed on a regular or periodic basis based upon the type of instrument being used and its sensitivity to factors such as the operating environment and the wear and tear of ongoing use. The type of instruments used in a particular facility and the manner of their use will largely determine the need for, and the frequency of, calibration, and the frequency of calibration is often prescribed by the instrument manufacturer. Therefore, proposed § 507.45(b)(4) would not specify a frequency for calibration.

b. Proposed § 507.45(c)—Records review. Proposed § 507.45(c) would require a review of specific records related to monitoring, corrective actions, and other verification activities within specified timeframes, by (or under the oversight of) a qualified individual, to ensure that the records are complete, the activities reflected in the records occurred in accordance with the food safety plan, the preventive controls are effective, and appropriate decisions were made about corrective actions. Proposed § 507.45(c)(1)(i) would require review of the monitoring and corrective action records within a week after the records are made. Proposed § 507.45(c)(1)(ii) would require review of the records related to calibration of instruments within a reasonable time after the records are made. (As discussed in section X.J, proposed § 507.55 would list the records that facilities must establish and maintain, including records that document the monitoring of preventive controls as required by § 507.39(c), corrective actions as required by § 507.42(d), and verification activities as required by § 507.45(f)). Proposed § 507.45(c) would implement section 418(f) of the FD&C Act and is consistent with the NACMCF HACCP guidelines, the Codex HACCP guidelines, and Federal HACCP regulations for seafood, juice, and meat and poultry.

Proposed § 507.45(c) would establish that the purpose of the review of records would be to ensure that the records are complete, the activities reflected in the records occurred in accordance with the food safety plan, the preventive controls are effective, and appropriate decision were made about corrective actions. The Agency tentatively concludes that review of the records required by proposed § 507.45(c)(1)(i) and (ii) would accomplish these purposes. Reviewing monitoring records can reveal whether they contain information on all the parameters that were to be monitored to determine whether a process is delivered in accordance with the food safety plan. For example, if the size of the animal food to be baked and the temperature and the time of baking are critical to the safety of the animal food, review of the monitoring records would demonstrate whether all three parameters were monitored and whether the values were within specified parameter values. Reviewing monitoring records can reveal whether a process followed the procedures specified in the facility's food safety plan (e.g., if the monitoring records show the temperature of every other batch of a baked animal food when the plan specified the measurement of every batch). Review of monitoring records also can reveal whether any information is missing, e.g., a designated lot number, so that the missing information can be quickly identified and added to the record if necessary. The Agency seeks comment on this proposal.

If the review of the records reveals that the records do not contain all information specified by the food safety plan, or that the procedure in the food safety plan was not followed, the facility will not be able to conclude that its preventive controls were implemented in accordance with its food safety plan for those activities. Because the food safety plan establishes the procedures needed to ensure preventive controls are effective, if the records review indicates that the plan is not being followed, e.g., the records are missing critical information or the activities were not performed as specified in the plan, the facility will not be able to conclude its preventive controls were effective. For example, if the records show that animal food particle size is not being determined or that the particles are too large, the minimum temperature of all parts of the particle may not occur to ensure control of pathogens such as *Salmonella* spp. If the plan requires determination of the baking temperature and time of each batch of product but the records do not show that the temperature was measured on all batches, the facility cannot be sure that the internal temperature of those batches is correct, again posing a potential risk from *Salmonella* spp. As a result, the facility would not be able to verify that its preventive controls are effectively and significantly minimizing or preventing the occurrence of identified hazards as required by section 418(f) of the FD&C Act.

Review of records can also reveal whether appropriate decisions were made about corrective actions. The review should determine whether all the corrective action procedures required by proposed § 507.42(a) have been followed, e.g., that actions are taken to prevent recurrence of the problem, that affected animal food has been evaluated for safety, and that affected animal food is prevented from entering commerce unless it can be determined that the animal food is not adulterated under section 402 of the FD&C Act. For example, a food safety plan may require that each package of product pass through a properly functioning metal detector and that the operator determine every two hours whether metal test pieces of a specified type and size are rejected when passed through the metal detector. If one of the test pieces was not rejected but production continued until a supervisor doing a verification check noted the problem, then corrective actions should have been taken and a corrective action record produced. A review of the corrective action records should reveal that all packages of product that passed through the metal detector since the last test showing the metal detector was functioning appropriately were held and passed through a functioning metal detector before being released into commerce. The records should also show that the metal detector was adjusted to reject the metal test pieces before it was used again to check product during production.

Proposed § 507.45(c) would require that the review of records be performed by (or under the oversight of) a qualified individual (see the discussion in section X.I regarding the activities that must be performed (or overseen) by a qualified individual as would be established in proposed § 507.50). The review of records is critical to assessing the facility's application of the preventive controls system and, thus, is fundamental to ensuring its successful operation.

Proposed § 507.45(c)(1)(i) would require review of the monitoring and corrective action records within a week after the records are made. Although proposed § 507.45(c)(1)(i) would establish a more frequent review of these records than recommended in the NACMCF guidelines (which recommend monthly verification of monitoring records and corrective action records), it is consistent with the Agency's HACCP regulations for seafood (§ 123.8(a)(3)(i) and (ii)) and juice (§ 120.11(a)(1)(iv)(A) and (B)), which require that the review of monitoring records and corrective action records occur within one week of the day that the records are made. Even for shelf-stable foods (e.g., low-acid canned foods and acidified foods) the Agency's experience has demonstrated that review of these kinds of records is a critical verification tool (60 FR 65096 at 65133, December 18, 1995). As discussed in the seafood HACCP final rule (60 FR 65096 at 65132), review of records needs to occur with sufficient frequency so as to ensure that any problems in the design and implementation of the HACCP plan are uncovered promptly and to facilitate prompt modifications. The concept is roughly that of a "feedback loop," with information coming out of the record review process in such a timely manner that it can have impact on the production of subsequent lots of the product. If a problem with product is discovered during a review of records, all product since the last review could be affected. Although verification prior to shipment provides a valuable added assurance, FDA explained in the preamble to the seafood HACCP final rule (60 FR 65096 at 65132) that with highly perishable products this is not always possible and that a weekly review of monitoring and corrective action records would provide for timely feedback of information and limit the amount of product impacted by any problems identified during the review of the records.

Proposed § 507.45(c)(1)(ii) would require review of the records related to calibration, within a reasonable time after the records are made. The review of calibration records will depend in part on the frequency with which calibrations occur, which will be established in the food safety plan. If calibrations occur daily, it would be reasonable to review these records weekly. Where several instruments are calibrated each month, a monthly review of all the calibrations would be reasonable. Consequently, FDA tentatively concludes that setting a specific frequency for review of these records is not warranted.

As noted previously, proposed § 507.45(c) would require a review of records in part to determine whether the preventive controls are effective. A review should determine whether monitoring and corrective actions have been done in accordance with the food safety plan and whether the instruments used in monitoring and verification were properly calibrated. If food safety activities appropriate to the facility have been conducted in accordance with the plan and this is reflected in the records, the facility thus verifies the preventive controls are effective, i.e., that its preventive controls are effectively and significantly minimizing or preventing the occurrence of identified hazards as required by Section 418(f) of the FD&C Act.

6. Proposed § 507.45(d)—Written Procedures for Verification Activities

Proposed § 507.45(d) would require that the owner, operator, or agent in charge of a facility establish and implement written procedures for the frequency of calibrating process monitoring instruments and verification instruments. The Agency is proposing to require written procedures for the frequency of calibration because the frequency of calibration will vary depending on the instrument and the process or verification activity that it pertains to.

The Agency is not proposing to require that written procedures be developed for all verification procedures. In some instances the records of verification activities provide the information needed to understand how the verification activity has been carried out and to assess whether the verification activity is adequately demonstrating that the preventive controls are effective in significantly minimizing or preventing the hazards reasonably likely to occur. For example, the Agency is not proposing to require written procedures for validation, verification of monitoring and corrective actions, or calibration of process monitoring instruments and verification instruments (other than for the frequency of calibration). Validation involves a variety of procedures, including evaluation of scientific and technical information and conducting laboratory and in-plant studies that generally do not follow a standardized protocol or approach. Records of monitoring and corrective actions provide the information needed to understand how the verification activity was carried out. In many instances the calibration of process monitoring instruments and verification instruments will be done by contract with other entities and the facility would not have access to the procedures used; having instruments calibrated and documenting the calibration provides the necessary assurance that such instruments will be accurate. However, the frequency of calibration must be specified to ensure that the instruments are calibrated on a schedule appropriate to the instrument and the process it controls.

Section 418(f) of the FD&C Act establishes certain requirements for verification, and section 418(h) of the FD&C Act requires that the procedures used by the facility to comply with the requirements of section 418 be included in the written plan. Requiring verification procedures to be written implements the requirements in section 418 of the FD&C Act and is consistent with the requirements in HACCP regulations for seafood, juice, and meat/poultry. For further discussion, see section XII.B.6 of the document for the proposed rule for preventive controls for human food (78 FR 3646).

7. Proposed § 507.45(e)—Reanalysis

a. Proposed § 507.45(e)—Reanalysis on the initiative of the owner, operator, or agent in charge of a facility. Proposed § 507.45(e)(1) would require that the owner, operator, or agent in charge of a facility conduct a reanalysis of the food safety plan:

- At least once every 3 years (proposed § 507.45(e)(1)(i));
- Whenever a significant change is made in the activities conducted at a facility operated by such owner, operator, or agent in charge if the change creates a reasonable potential for a new hazard or creates a significant increase in a previously identified hazard (proposed § 507.45(e)(1)(ii));
- Whenever the owner, operator or agent in charge becomes aware of new information about potential hazards associated with the animal food (proposed § 507.45(e)(1)(iii));
- Whenever a preventive control is not properly implemented and a specific corrective action procedure has not been established (proposed § 507.45(e)(1)(iv));
- Whenever a preventive control is found to be ineffective (proposed § 507.45(e)(1)(v)); and
- Whenever FDA requires a reanalysis in response to newly identified hazards and developments in scientific understanding (proposed § 507.45(e)(1)(vi).

For example, if a facility that conducts baking operations for pet treats makes design changes to its oven to increase product throughput, the facility would be required to reanalyze its food safety plan because a design change to equipment that is used to control a hazard that is reasonably likely to occur would be a significant change in the activities conducted at the facility.

The owner, operator or agent in charge of a facility may become aware of a problem due to the finding of a hazard in an animal food as the result of testing by a regulatory agency (Federal, State, tribal, or foreign government) that would require an analysis of the food safety plan to ensure the hazard is significantly minimized or prevented by appropriate preventive controls. In addition, new hazards can emerge, e.g., as identified through the investigation of outbreaks. For example in 2006–2007 there was an outbreak of salmonellosis due to contamination of peanut butter with *Salmonella* Tennessee (Ref. 83). This was the first outbreak of food borne illness caused by peanut butter consumption in the U.S. and it demonstrated the need for manufacturers to address the hazard of *Salmonella* spp. in this product and in products into which peanut butter is added, such as pet treats. Information about outbreaks and ensuing product recalls is widely disseminated, including on FDA's Web site, and modern communication tools make it possible for the owner, operator, or agent in charge of a facility to receive such information automatically. For additional discussion related to the proposed requirement that the owner, operator, or agent in charge of a facility conduct a reanalysis whenever such owner, operator or agent becomes aware of new information about potential hazards associated with the food, see the discussion in section X.G.7.b of proposed § 507.45(e)(1)(vi), which would provide that FDA may require a reanalysis of the food safety plan to respond to new hazards and developments in scientific understanding.

As noted in section X.F of this preamble, proposed § 507.42(b)(4) would require that the owner, operator, or agent in charge of a facility reanalyze the food safety plan in accordance with proposed § 507.45(e) to determine whether modification of the food safety plan is required if a preventive control is not properly implemented or is found to be ineffective, and a specific corrective action has not been established. If the owner, operator, or agent in charge of a facility has not identified a specific failure as a foreseeable occurrence, the deviation may be the result of a system-wide problem that is not being properly addressed by the food safety plan (e.g., ineffective preventive controls). Thus, an unforeseen failure for which a corrective action was not identified may indicate an ineffective preventive control, and a reanalysis of the food safety plan is warranted. Similarly, when information arises indicating that the preventive control has not been effective in significantly minimizing or preventing a hazard from occurring, a reanalysis must be conducted to determine if the food safety plan should be modified to ensure that the preventive controls implemented are adequate to significantly minimize or prevent a hazard identified as reasonably likely to occur.

Proposed § 507.45(e) would implement section 418(f)(5) and (i) of the FD&C Act and is consistent with the NACMCF HACCP guidelines, the Codex HACCP guidelines, the Codex validation guidelines, and Federal HACCP regulations for seafood, juice, and meat and poultry. A discussion on "reanalysis" (or "reassessment of the hazard analysis" as it is called) in HACCP systems can be found in section XII.G.7 of the document for the proposed rule for preventive controls for human food (78 FR 3646).

The requirement in proposed § 507.45(e)(1) that the periodic reanalysis of the food safety plan occur at least once every 3 years is explicitly required by section 418(i) of the FD&C Act. The Agency tentatively concludes that, as a practical matter, the proposed requirement for reanalysis whenever a significant change is made in the activities conducted at a facility if the change creates a reasonable potential for a new hazard or a significant increase in a previously identified hazard makes it likely that reanalysis would occur more frequently than every 3 years because such changes are likely to occur more frequently than every 3 years.

b. Proposed § 507.45(e)(1)(vi)—Reanalysis on the initiative of FDA. Proposed § 507.45(e)(1)(vi) establishes that FDA may require a reanalysis of the food safety plan to respond to new hazards and developments in scientific understanding. Proposed § 507.45(e)(1)(vi) would implement section 418(i) of the FD&C Act, which provides in relevant part that ''[t]he Secretary may require a reanalysis . . . to respond to new hazards and developments in scientific understanding . . . .'' As discussed in section X.G.7.a, new hazards can emerge, e.g., as identified through the investigation of outbreaks of foodborne illness by CDC or other public health agencies. In addition, new developments can occur in the scientific understanding of existing or potential hazards, e.g., if scientists and animal food safety regulatory agencies develop a better understanding of the causes of these events. For example, the outbreak from *Salmonella* Tennessee in peanut butter resulted in a greater understanding of the risks posed by environmental contamination and the importance of control of water in facilities producing low-moisture foods (Refs. 84 and 85. Information submitted to the RFR, which is a relatively recent addition to the regulatory framework for food safety, has the potential to identify new hazards or routes of contamination even before outbreaks occur.

c. Proposed § 507.45(e)(2)—Implementation of additional controls. Proposed § 507.45(e)(2) would require that the owner, operator, or agent in charge of a facility complete the required reanalysis and implement any additional preventive controls needed to address the hazard identified, if any, before the change in activities at the facility is operative or, when necessary, during the first 6 weeks of production. The purpose of the reanalysis is to identify the need for, and implement, preventive controls in light of a reasonable potential for a new hazard, or a significant increase in a previously identified hazard, that is reasonably likely to occur. It follows that the preventive controls must be in place before making the change that creates the potential for a new hazard or a significant increase in a previously identified hazard. As with initial validation in proposed § 507.45(a)(1)(i), the Agency is proposing to provide the first 6 weeks of production, when necessary, to implement any additional preventive controls to allow facilities to methodically collect data and information during production to ensure the needed change can be implemented in the facility. The Agency seeks comment on this timeframe. Proposed § 507.45(e)(2) would implement section 418(i) of the FD&C Act.

d. Proposed § 507.45(e)(3)—Revision of the food safety plan. Proposed § 507.45(e)(3) would require that the owner, operator, or agent in charge of a facility revise the written food safety plan if a significant change is made or document the basis for the conclusion that no additional or revised preventive controls are needed. Proposed § 507.45(e)(3) would implement section 418(i) of the FD&C Act, which requires that the written plan be revised ''if . . . a significant change is made or document the basis for the conclusion that no additional or revised preventive controls are needed.'' As discussed in section X.B of this document, the written hazard analysis is required even if the conclusion of the analysis is that there are no hazards reasonably likely to occur. It is also important to document that a reanalysis has been conducted even if no change has been made, as required by section 418(i) of the FD&C Act. Such documentation demonstrates that a facility has considered all relevant information on the safety of the products being produced, including new information that has become available since the last analysis, and determined that current procedures for implementing preventive controls are adequate to significantly minimize or prevent hazards that are reasonably likely to occur.

e. Proposed § 507.45(e)(4)—Requirement for a qualified individual. Proposed § 507.45(e)(4) would require that the reanalysis be performed, or overseen, by a qualified individual. Proposed § 507.45(e)(4) is consistent with proposed § 507.30(b) which would require that the food safety plan be developed by a qualified individual. The Agency tentatively concludes that the same qualifications are needed whether initially conducting a hazard analysis and establishing a food safety plan, or reanalyzing a hazard analysis and plan.

8. Proposed § 507.45(f)—Requirement for Records for Verification

Proposed § 507.45(f) would require that all verification activities taken in accordance with this section be documented in records and would implement section 418(g) of the FD&C Act.

H. Proposed § 507.48—Modified Requirements That Apply to a Facility Solely Engaged in the Storage of Packaged Animal Food That Is Not Exposed to the Environment

1. Requirements of Section 418 of the FD&C Act

Briefly, as relevant to proposed § 507.48, specific provisions of section 418 of the FD&C Act require, in relevant part, that the owner, operator, or agent in charge of a facility:

- Identify and evaluate known or reasonably foreseeable hazards that may be associated with the facility and develop a written analysis of the hazards (section 418(b) of the FD&C Act);
- Identify and implement preventive controls to provide assurances that hazards identified in the hazard analysis will be significantly minimized or prevented and the food manufactured, processed, packed, or held by such facility will not be adulterated under section 402 of the FD&C Act (section 418(c) of the FD&C Act);
- Monitor the effectiveness of the preventive controls implemented under section 418 (c) of the FD&C Act to provide assurances that the outcomes described in section 418(c) shall be achieved (section 418(d) of the FD&C Act);
- Establish procedures to ensure that, if the preventive controls implemented under section 418(c) of the FD&C Act are not properly implemented or are found to be ineffective, appropriate action is taken to reduce the likelihood of recurrence of the implementation failure; all affected food is evaluated for safety; and all affected food is prevented from entering into commerce if the owner, operator or agent in charge of such facility cannot ensure that the affected food is not adulterated under section 402 of the FD&C Act (section 418(e) of the FD&C Act);
- Verify that the preventive controls are adequate to control the hazards the owner, operator, or agent is conducting monitoring and is making appropriate decisions about corrective actions and the preventive controls are effectively and significantly minimizing or preventing the occurrence of identified hazards and there is documented, periodic reanalysis of the plan under section 418(i) of the FD&C Act to ensure that the plan is still relevant to the raw materials, conditions and processes in the facility, and new and emerging threats (section 418(f) of the FD&C Act);
- Maintain, for not less than 2 years, records documenting the monitoring of the preventive controls instances of nonconformance material to food safety

and instances when corrective actions were implemented (section 418(g) of the FD&C Act);

- Prepare a written plan that documents and describes the procedures used by the facility to comply with the requirements of section 418 of the FD&C Act, including analyzing the hazards and identifying the preventive controls adopted to address those hazards section 418(h) of the FD&C Act);
- Conduct a reanalysis under section 418(b) of the FD&C Act whenever a significant change is made in the activities conducted at a facility operated by such owner, operator, or agent if the change creates a reasonable potential for a new hazard or a significant increase in a previously identified hazard or not less frequently than once every 3 years, whichever is earlier (section 418(i) of the FD&C Act).

In addition to these requirements directed to the owner, operator, or agent in charge of a facility, section 418(m) of the FD&C Act provides, in relevant part, that the Secretary may, by regulation, exempt or modify the requirements for compliance under section 418 of the FD&C Act with respect to facilities that are solely engaged in the storage of packaged foods that are not exposed to the environment.

2. Approach to Modified Requirements Under Section 418(m) of the FD&C Act

As discussed in section VIII.E of this document, proposed § 507.10 would both provide that proposed part 507 subpart C does not apply to a facility solely engaged in the storage of packaged animal food that is not exposed to the environment (proposed § 507.10(a)) and establish that such a facility is subject to modified requirements in proposed § 507.48 (proposed § 507.10(b)). In the remainder of the discussion of these modified requirements, the Agency refers to "packaged food that is not exposed to the environment" as "unexposed packaged animal food," and to "unexposed refrigerated packaged animal food that requires time/temperature control for safety" as "unexposed refrigerated packaged TCS animal food." As noted in section VIII.E, the Agency considers "not exposed to the environment" and "unexposed" to mean that the animal food is in a form that prevents any direct human contact with the food. The modified requirements in proposed § 507.48 would apply to unexposed refrigerated packaged TCS animal food. In essence, proposed § 507.48 distinguishes between unexposed packaged animal food and unexposed refrigerated packaged TCS animal food. This distinction is based on hazards that are reasonably likely to occur during the storage of unexposed refrigerated packaged TCS animal food, but are not reasonably likely to occur during the storage of unexposed packaged animal food that does not require time/temperature control for safety.

When an unexposed packaged animal food is a refrigerated TCS animal food, the principal hazard for the unexposed refrigerated packaged TCS animal food is the potential for the growth of, or toxin production by, microorganisms of animal or human health significance. Information about this hazard for TCS foods in general (i.e., not limited to unexposed packaged animal food) is widely available (Refs. 39, 40, and 86). In brief, the need for time/temperature control is primarily determined by: (1) The potential for contamination with microorganisms of animal or human health significance and (2) the potential for subsequent growth and/or toxin production. Refrigeration has long been used to retard deterioration of the flavor, color, and texture of foods including animal food. More importantly, refrigeration helps maintain the microbiological safety of potentially hazardous foods (62 FR 8248; February 24, 1997).

Failure to maintain animal food at appropriate temperatures may result in the growth of microorganisms that may have contaminated the food before, or at the time of, harvest or during processing, handling, or storage. The rate of growth of these microorganisms is reduced as the storage temperature is lowered. Proper refrigeration, therefore, prevents or slows the growth of animal and human pathogens and spoilage microorganisms and reduces the likelihood of foodborne illness (62 FR 8248). A review of the factors that influence microbial growth and an analysis of microbial hazards related to time/temperature control of foods for safety can be found in a report (issued by the Institute of Food Technologists (IFT) under contract to FDA) on the Evaluation and Definition of Potentially Hazardous Foods (Ref. 86). The IFT report describes properties of common food commodities and the microbiological hazards that may occur from consuming particular food commodities, emphasizing microbial concerns that would be associated with temperature abuse of the products. The IFT report discusses foods for which time/temperature control may be necessary for safety (Ref. 86). Most types of animal food that are stored refrigerated have not been processed to eliminate pathogenic sporeformers, including *Clostridium botulinum,* and *Bacillus* spp. If refrigerated animal food is exposed to high enough temperatures for sufficient time, these sporeformers may begin to grow and produce toxins. Some strains of *C. botulinum* and *Bacillus* spp. can grow at refrigeration temperatures, e.g., some strains of *B. cereus* grow at 39 °F (4 °C) and some strains of *C. botulinum* grow at 38 °F (3.3 °C) (Ref. 87).

Examples of refrigerated foods that are capable of supporting the growth of pathogenic sporeformers such as *Bacillus,* spp. and *C. botulinum* include many refrigerated food for dogs and cats. Producers of refrigerated animal food minimize the contamination of the food with pathogens to the extent possible, particularly if the pathogen can grow under refrigeration conditions. Growth of pathogens is very slow under refrigeration, and the lower the temperature the longer the time for growth (Ref. 86). Conversely, as refrigeration temperature increases, the growth rate of strains of pathogens that grow slowly under refrigeration increases and animal food temperatures may get high enough that pathogens that cannot grow at normal refrigeration temperatures (generally in the range of 41–45 °F (5 °C–7 °C)) begin to grow (Ref. 86). For example, the strains of *C. botulinum* that have caused most of the outbreaks in the United States do not grow and produce toxin until the temperature reaches 50 °F (10 °C) (Ref. 78). Additional information about the time/temperature control of food to address the potential for microorganisms of animal or human health significance to grow or produce toxins is available in books on food microbiology that are available for purchase.

Such information is sufficiently well-known and accepted that the Agency tentatively concludes that the outcome of each individual hazard analysis for an unexposed refrigerated packaged TCS animal food, conducted by the owner, operator, or agent in charge of each individual facility solely engaged in the storage of unexposed packaged animal food, would be the same. That outcome would be that the potential for the growth of, or toxin production by, microorganisms of animal or human health significance is a hazard reasonably likely to occur in any unexposed refrigerated packaged TCS animal food. Likewise, information about appropriate preventive controls for this hazard is widely available (Refs. 41 and 78). Such information is sufficiently well-known and accepted that the Agency tentatively concludes that the appropriate preventive control selected by each individual facility solely engaged in the storage of unexposed packaged animal food would be adequate controls on the temperature of any unexposed refrigerated packaged TCS animal food.

In light of the general recognition of the hazard that is reasonably likely to occur in a refrigerated packaged TCS animal food and the appropriate preventive control for that hazard, the Agency tentatively concludes that it is appropriate to specify the hazard and appropriate preventive control in the regulation. Under this approach, it would not be necessary for each individual facility solely engaged in the storage of unexposed packaged animal food to conduct its own hazard analysis and reach its own conclusion about the hazard and the appropriateness of temperature control to significantly minimize or prevent the growth of, or toxin production by, microorganisms of animal or human health significance. Instead, what would remain for the facility to do to comply with section 418 of the FD&C Act for the activity of storing an unexposed refrigerated packaged TCS animal food would be a subset of the requirements for hazard analysis and risk-based preventive controls that would be established in proposed subpart C to implement section 418 of the FD&C Act. None of these requirements would require a qualified individual. This subset of requirements would be to:

- Implement temperature controls (section 418(c) of the FD&C Act);
- Monitor temperature (section 418(d) of the FD&C Act);
- Take appropriate corrective actions when there is a problem with temperature control (section 418(e) of the FD&C Act);
- Conduct applicable verification activities (review of records) (section 418(f) of the FD&C Act); and
- Establish and maintain certain records (section 418(g) of the FD&C Act).

The Agency seeks comment on the proposed list of modified requirements.

The Agency also tentatively concludes that it would not be necessary for each individual facility solely engaged in the storage of unexposed packaged animal food to conduct the reanalysis specified in section 418(i) of the FD&C Act with respect to storing an unexposed refrigerated packaged TCS animal food. As discussed in section X.G of this document, reanalysis would apply in determining whether to apply any additional preventive controls and in determining whether to update the written plan. Under this approach, FDA would have identified the preventive control, and it would be FDA's responsibility, through rulemaking, to require any additional preventive control. Likewise, under FDA's approach, the facility would not be required to develop a food safety plan and, therefore, would not need to update the plan. If, for example, the facility changes its procedures for temperature control, the specific activities that the facility would be required to conduct (monitoring temperature; taking appropriate corrective actions if there is a problem with temperature control; conducting applicable verification activities; and establishing and maintaining appropriate records) would be adequate to address the change in procedure for temperature control.

3. Proposed § 507.48—Modified Requirements That Apply to a Facility Solely Engaged in the Storage of Packaged Animal Food That Is Not Exposed to the Environment

Proposed § 507.48(a) would require that the owner, operator, or agent in charge of a facility solely engaged in the storage of packaged animal food that is not exposed to the environment conduct certain activities for any such refrigerated packaged animal food that requires time/temperature control to significantly minimize or prevent the growth of, or toxin production by, microorganisms of animal or human health significance. Briefly, those activities would encompass:

- Establishing and implementing temperature controls (proposed § 507.48(a)(1));
- Monitoring the temperature controls (proposed § 507.48(a)(2));
- If there is a problem with the temperature controls for such refrigerated packaged animal food, taking appropriate corrective actions (proposed § 507.48(a)(3));
- Verifying that temperature controls are consistently implemented (proposed § 507.48(a)(4)); and
- Establishing and maintaining certain records (proposed § 507.48(a)(5)).

More specifically, proposed § 507.48(a)(1) would require that the owner, operator, or agent in charge of a facility subject to proposed § 507.48 establish and implement temperature controls adequate to significantly minimize or prevent the growth of, or toxin production by, microorganisms of animal or human health significance in an unexposed refrigerated packaged TCS animal food. There are two fundamental questions that the owner, operator, or agent in charge of a facility subject to proposed § 507.48 would need to know the answers to in order to comply with proposed § 507.48 for any given unexposed refrigerated packaged animal food:

- Is the animal food a TCS food?
- If the animal food is a TCS food, what is the appropriate temperature for storage of the food?

The two primary ways in which the owner, operator, or agent in charge of a facility subject to proposed § 507.48 can obtain the answers to these questions are through: (1) Information provided by the manufacturer, processor, or packer of the animal food, either in documents exchanged between the parties in the course of business or by label statements placed on the animal food by the manufacturer, processor, or packer of the food and (2) applicable scientific and technical support literature.

As discussed in section VIII.E, a citizen petition submitted to FDA (Docket No. FDA–2011–P–0561) asserted that facilities work closely with the food manufacturers to understand the conditions and controls that need to be utilized to ensure the quality of the foods they store and distribute and, in many cases, those conditions and controls are formalized in written contracts. If the conditions for storage are not formalized in written contracts or by other means (e.g., through documents of the trade that travel with a food product when it moves within the supply chain), information relevant to safe storage of the food may be provided by the manufacturer, processor, or packer of the food on the food label. For example, in 1997 FDA published guidelines for labeling food that needs refrigeration by consumers due to the potential for the food to be rendered unsafe due to the growth of infectious or toxigenic microorganisms if "temperature abused" (62 FR 8248). FDA recommended that foods requiring refrigeration by the consumer for safety be labeled "IMPORTANT Must be Kept Refrigerated to Maintain Safety" (62 FR 8248 at 8251) and that foods that are intended to be refrigerated but that do not pose a safety hazard if temperature abused be labeled more simply, e.g.; "Keep refrigerated." Such labeling can provide facilities with the information to identify TCS animal food. The Agency tentatively concludes that similar food safety principles applied in human food storage would be relevant to animal food. Further, the Agency tentatively concludes that it would be rare for a facility solely engaged in the storage of unexposed packaged animal food to not have information regarding whether a refrigerated packaged food requires time/temperature control for safety and, if so, what specific temperature controls are necessary for safe storage of the food. The Agency requests comment on this tentative conclusion.

In a situation where the owner, operator or agent in charge of a facility does not have information from the manufacturer, processor, or packer of the food about whether an unexposed refrigerated packaged animal food requires time/temperature control for safety and, if so, what specific temperature controls are necessary for safe storage of the food, the owner, operator, or agent in charge of the facility could either consult the scientific and technical literature to determine whether a particular food is a TCS animal food or assume that any unexposed refrigerated packaged food is a TCS animal food. Information about food that is TCS animal food, and about the appropriate temperatures to address the potential for microorganisms of animal or human health significance to grow or produce toxin, in food are well-established in the scientific literature. Documents prepared by or on behalf of FDA regarding appropriate time/temperature controls for safety (Refs. 86 and 87) provide numerous references to the primary scientific literature and serve as the basis for time/temperature controls for a variety of foods including animal food. The two temperatures commonly cited in these documents as maximum temperatures for safe storage of refrigerated food are 41 °F (5 °C) and 45 °F (7 °C). The cited maximum temperature depends on the type of food; in some cases, a maximum storage temperature is established through rulemaking in a regulation. For example:

- FDA regulations for the prevention of *Salmonella* Enteritidis in shell eggs during production, storage, and transportation (§ 118.4(e) (21 CFR 118.4(e))) and for refrigeration of shell eggs held for retail distribution (21 CFR 115.50(b)(2)) require that eggs be held and transported at a temperature not to exceed 45 °F (7 °C).
- The PMO provides for pasteurized Grade ''A'' milk and milk products to be held at 45 °F (7 °C) (Ref. 77).
- The FDA Food Code, which has been widely adopted in state laws, recommends holding most potentially hazardous (TCS) food at 41 °F (7 °C) or lower (Ref. 88).

Storage of refrigerated food at or below one of these two temperatures (i.e., 41 °F (5 °C) or 45 °F (7 °C)) consistent with storage temperatures required by regulation or recommended in widely adopted documents such as the PMO and the FDA Food Code would satisfy proposed § 507.48(a).

The Agency considers frozen animal food to be a subset of refrigerated animal food. The temperature and time required for a frozen animal food to become unsafe would result in significant quality issues for such food. Although there have been occasional problems with frozen animal food being subject to temperatures that allow some thawing in storage and distribution, the Agency is not aware of situations in which frozen animal food has been associated with the food becoming unsafe. Thus, the Agency tentatively concludes that it would be rare for an unexposed frozen packaged animal food to be a TCS animal food.

Proposed § 507.48(a)(2) would require that the owner, operator, or agent in charge of a facility solely engaged in the storage of unexposed packaged animal food monitor the temperature controls established for unexposed refrigerated packaged TCS animal food with sufficient frequency to provide assurance that they are consistently performed. Monitoring can be done by use of a continuous temperature-recording device (e.g., a recording thermometer) that indicates and records the temperature accurately within the refrigeration compartment with a visual check of the recorded data at least once per day. Monitoring as would be required by proposed § 507.48(a)(2) would provide the owner, operator, or agent in charge of the facility with factual information with which to judge whether the temperature control is operating as intended. Proposed § 507.48(a)(2) is modified relative to the analogous monitoring requirement that would be established in proposed § 507.39(a) in subpart C in that proposed § 507.48(a)(2) would not require written procedures for monitoring. The records of monitoring (which would be required by proposed § 507.48(a)(5)(i)) would demonstrate the frequency of monitoring. The Agency requests comment on whether there would be a benefit to requiring a facility to develop written procedures for monitoring temperature.

Proposed § 507.48(a)(3) would require that, if there is a problem with the temperature controls for unexposed refrigerated packaged TCS animal food, the owner, operator, or agent in charge of a facility solely engaged in the storage of unexposed packaged animal food take appropriate corrective actions to correct a problem with the control of temperature for any refrigerated packaged animal food and reduce the likelihood that the problem will recur (proposed § 507.48(a)(3)(i)); evaluate all affected animal food for safety (proposed § 507.48(a)(3)(ii)); and prevent the animal food from entering commerce, if the owner, operator, or agent in charge of a facility cannot ensure the affected animal food is not adulterated under section 402 of the FD&C Act (proposed § 507.48(a)(3)(iii)). Such corrective actions would be necessary if, for example, there was a failure to maintain adequate temperature control. Proposed § 507.48(a)(3) is modified relative to the analogous proposed requirement for corrective actions that would be established in proposed § 507.42(a) in subpart C in that proposed § 507.48(a)(3) would not require written procedures for corrective actions. In essence, there is a single action to correct the problem (i.e., to restore temperature control), followed by the need to evaluate the animal food for safety and to prevent animal food from entering commerce when appropriate. The corrective actions taken, including information to document that product was not exposed to temperatures and times that would compromise the safety of the product, would be documented in records subject to agency review. It may be necessary for the owner, operator, or agent in charge of the facility to consult with the applicable manufacturer, processor, or packer of the animal food to determine the appropriate disposition of the food.

Proposed § 507.48(a)(4)(i) would require that the owner, operator, or agent in charge of a facility solely engaged in the storage of unexposed packaged animal food verify that temperature controls are consistently implemented by calibrating temperature monitoring and recording devices. As discussed in section X.G.5.b of this document, calibration provides assurance that an instrument is measuring accurately. If these instruments are not properly calibrated, the values they provide may not provide the necessary assurance temperatures are adequate to significantly minimize or prevent the growth of, or toxin production by, microorganisms of animal or human health significance in an unexposed refrigerated packaged TCS animal food. Proposed § 507.48(a)(4)(i) is analogous to proposed § 507.45(b)(3)(ii) in subpart C, which would establish a verification requirement for calibration of process monitoring instruments and verification instruments.

Proposed § 507.48(a)(4)(ii) would require that the owner, operator, or agent in charge of a facility solely engaged in storage of unexposed packaged animal food verify that temperature controls are consistently implemented by reviewing records of calibration within a reasonable time after the records are made. As discussed in section X.G.5.e of this document, the purpose of the review of records would be to ensure that the records are complete and that the preventive controls are effective. If temperature monitoring and recording devices are not properly calibrated, the temperature controls may not be effective. As discussed in section X.G.5.e, the review of calibration records will depend in part on the frequency with which calibrations occur.

Proposed § 507.48(a)(4)(iii) would require that the owner, operator, or agent in charge of a facility solely engaged in storage of unexposed packaged animal food verify that temperature controls are consistently implemented by reviewing the records of monitoring and actions taken to correct a problem with the control of temperature within a week after the records are made. As discussed in section X.G.5.e, the purpose of the review of records would be to ensure that the records are complete, that the temperatures recorded were adequate to significantly minimize or prevent the growth of, or toxin production by, microorganisms of public animal or human significance in an unexposed refrigerated packaged TCS animal food, and that appropriate actions were taken to correct any problem with the control of temperature for any unexposed refrigerated packaged TCS animal food. A weekly review of monitoring and corrective action records would provide for timely feedback of information and limit the amount of product impacted by any problems identified during the review of the records. Proposed § 507.48(a)(4)(iii) is analogous to proposed § 507.45(c)(1)(i) in subpart C, which would establish a verification requirement for review of records of monitoring and corrective action records within a week after the records are made.

Proposed § 507.48(a)(4) is modified relative to the analogous proposed verification requirements in proposed § 507.45 in that proposed § 507.48(a)(4) would not require validation or reanalysis. There is a single control to verify, which limits the need for many of the verification procedures that might otherwise apply. As noted above, the temperatures to control growth of microbial pathogens are well documented and do not require validation that they are effective in controlling the potential for microorganisms of animal or human health significance to grow, or produce toxin, in animal food The reasons for not requiring reanalysis were discussed previously in this section. Proposed § 507.48(a)(4) is also modified relative to the analogous proposed verification requirements in proposed § 507.45 in that proposed § 507.48(a)(4) would not require that a qualified individual perform or oversee the review of records of calibration or records of monitoring and actions taken to correct a problem with the control of temperature. The nature of these records does not require the qualifications that would be required under proposed § 507.50(b).

Proposed § 507.48(a)(5) would require that the owner, operator, or agent in charge of a facility solely engaged in storage of unexposed packaged animal food establish and maintain records documenting the monitoring of temperature controls for any unexposed refrigerated packaged TCS animal food (proposed § 507.48(a)(5)(i)); records of corrective actions taken when there is a problem with the control of temperature for any unexposed refrigerated packaged TCS animal food (proposed § 507.48(a)(5)(ii)); and records documenting verification activities (proposed § 507.48(a)(5)(iii)). The records that document monitoring would be used to verify that the temperature controls are effectively and significantly minimizing or preventing the growth of, or toxin production by, microorganisms of animal or human health significance. The records that document corrective actions would be used to verify that appropriate decisions about corrective actions are being made and appropriate corrective actions are being taken. The records that document verification activities would be used to document that this key element of a food safety plan has been implemented. These records would be necessary to demonstrate compliance with the requirements and as such would be useful to inspectors and auditors. Proposed § 507.48 (a)(5) is analogous to provisions in proposed §§ 507.36(d)(2)(iv), 507.39(c), and 507.45(e) in subpart C, which would require documentation of monitoring, corrective actions, and verification activities, respectively.

Proposed § 507.48(b) would establish that the records that a facility must establish and maintain under proposed § 507.48(a)(5) are subject to the requirements of proposed subpart F. Proposed subpart F would establish requirements that would apply to all records that would be required under part 507. FDA describes the requirements of proposed subpart F in section XII. Proposed § 507.48(b) is analogous to proposed § 507.55(b) in subpart C.

I. Proposed § 507.50—Requirements Applicable to a Qualified Individual

Proposed § 507.50(a) would require that one or more qualified individuals prepare the food safety plan (proposed § 507.30), validate the preventive controls (proposed § 507.45(a)), review records for implementation and effectiveness of preventive controls (proposed § 507.45(c)), and perform reanalysis of the food safety plan (proposed § 507.45(e)). The Agency has discussed the basis for requiring that a trained individual perform or oversee these functions in its discussion of each applicable proposed provision. The Agency is listing the functions that must be performed by a trained individual in § 507.50(a) for simplicity and are not imposing any additional requirement through this list. A single individual with appropriate qualifications could perform all of the listed functions, but there would be no requirement for the same individual to perform all the listed functions.

Proposed § 507.50(b) would establish the qualification requirements applicable to a qualified individual. To be qualified, an individual must have successfully completed training in the development and application of risk-based preventive controls at least equivalent to that received under a standardized curriculum recognized as adequate by the FDA, or be otherwise qualified through job experience to develop and apply a food safety system. Training or job experience is essential to the effective development and implementation of a hazard analysis and risk-based preventive controls. Only a trained individual or individual qualified by job experience is capable of effectively executing certain activities, such as identifying hazards that are reasonably likely to occur; identifying preventive controls that will address those hazards; evaluating scientific and technical information to determine whether the food safety plan, when properly implemented, will effectively control the hazards that are reasonably likely to occur; determining the maximum or minimum value, or combination of values, to which any biological, chemical, physical, or radiological parameter must be controlled to significantly minimize or prevent a hazard that is reasonably likely to occur; determining whether monitoring procedures and corrective action procedures are appropriate; and determining whether specific corrective actions have been appropriate and effective. In addition, the products produced by the animal food industry are diverse, and the hazards that are reasonably likely to occur in a particular facility depend on a range of factors that vary from one facility to the next. The Agency requests comment on the scope of the qualifications identified.

FDA will be working with an animal food alliance to develop a standardized curriculum for any final rule establishing requirements for hazard analysis and risk-based preventive controls. Having a standardized curriculum on which facilities, as well as private organizations and academia that conduct training, can base their materials and training would provide a framework to ensure minimum training requirements are met.

Proposed § 507.50(b) also would provide that the qualified individual may be, but is not required to be, an employee of the facility. FDA expects that some facilities may rely on assistance from qualified individuals that are not employees of the facility, such as individuals associated with universities, trade associations, and consulting companies. Proposed § 507.50(b) is consistent with HACCP regulations for seafood and juice, which have virtually identical requirements (§§ 123.10 and 120.13(b), respectively). The option in proposed § 507.50(b) would provide flexibility to facilities subject to the rule. Such flexibility may be particularly important for those facilities that have limited technical expertise.

Proposed § 507.50(c) would require that all applicable training be documented in records, including the date of the training, the type of training, and the person(s) trained. Such records would be a simple mechanism to demonstrate that a person has successfully completed training in the development and application of risk-based preventive controls at least equivalent to that received under a standardized curriculum recognized as adequate by the FDA, as would be required under proposed § 507.50(b) should the qualified individual not be otherwise qualified through job experience to develop and apply an animal food safety system.

J. Proposed § 507.55—Records Required for Subpart C

1. Requirements of Section 418 of the FD&C Act

Section 418(g) of the FD&C Act, in relevant part, specifies that the owner, operator, or agent in charge of a facility shall maintain, for not less than 2 years, records documenting the monitoring of the preventive controls implemented under section 418(c) of the FD&C Act, instances of nonconformance material to food safety, the results of testing and other appropriate means of verification under section 418(f)(4) of the FD&C Act, instances when corrective actions were implemented, and the efficacy of preventive controls and corrective actions.

Section 418(h) of the FD&C Act, in relevant part, specifies that the owner, operator, or agent in charge of a facility shall prepare a written plan that documents and describes the procedures used by the facility to comply with the requirements of section 418 of the FD&C Act, including analyzing the hazards under section 418(b) of the FD&C Act and identifying the preventive controls adopted under section 418(c) of the FD&C Act to address those hazards. Section 418(h) of the FD&C Act also specifies that the written plan, together with the documentation described in section 418(g) of the FD&C Act, shall be made promptly available to a duly authorized representative of the Secretary upon oral or written request.

2. Proposed § 507.5—Records Required for Subpart C

Proposed § 507.55(a)(1) through (a)(5) would require that the owner, operator, or agent in charge of a facility establish and maintain the following records:

- The written food safety plan, including the written hazard analysis, preventive controls, monitoring procedures, corrective action procedures, verification procedures, and recall plan;
- Records that document the monitoring of preventive controls;
- Records that document corrective actions;
- Records that document verification, including, as applicable, those related to validation; monitoring; corrective actions; calibration of process monitoring and verification instruments; records review; and reanalysis; and
- Records that document applicable training for the qualified individual.

Proposed § 507.55(a) would not establish any new requirements, but merely make it obvious at a glance what records are required under proposed part 507, subpart C.

Proposed § 507.55(b) would provide that the records that the owner, operator, or agent in charge of a facility must establish and maintain are subject to the requirements of proposed part 507, subpart F. As discussed in section XII, proposed subpart F would provide the general requirements that apply to all records required to be established and maintained by proposed part 507, including provisions for retention of records and for making records available for official review.

K. Request for Comment on Additional Preventive Controls and Verification Procedures Not Being Proposed

1. Overview

As discussed in section II.C.2, section 418(n) requires FDA to establish science-based minimum standards for, among other things, implementing preventive controls. In addition, section 418(f) requires certain verification of those preventive controls. In this section of the preamble, the Agency discusses several preventive controls (i.e., supplier controls) and verification measures (i.e., environmental and product testing programs) that FDA is not including as provisions in proposed part 507, subpart C.

As the Agency discussed in section X.C.1, section 418(c) requires the owner, operator, or agent in charge of a facility to identify and implement preventive controls. Section 418(o)(3) defines "preventive controls" to mean "those risk-based, reasonably appropriate procedures, practices and processes that a person knowledgeable about the safe manufacturing, processing, packing, or holding of food would employ to significantly minimize or prevent [identified hazards] and that are consistent with current scientific understanding of safe food manufacturing, processing, packing, or holding . . . ." Section 418(o)(3) indicates that those procedures, practices, and processes may include environmental monitoring, supplier verification activities, and certain sanitation controls. In addition, environmental and product testing programs are set out in section 418(f)(4): Section 418(f)(4) requires that the owner, operator, or agent in charge of a facility "verify that . . . the preventive controls . . . are effectively and significantly minimizing or preventing the occurrence of identified hazards, including through the use of environmental and product testing programs and other appropriate means."

The Agency believes that the preventive controls and verification measures discussed in this section are an important part of a modern animal food safety system. The Agency believes that the preventive controls discussed in this section (i.e., a supplier approval and verification program), when implemented appropriately in particular facilities, are "risk-based, reasonably appropriate procedures, practices, and processes that a person knowledgeable about the safe manufacturing, processing, packing, or holding of food would employ to significantly minimize or prevent [identified hazards] and that are consistent with current scientific understanding of safe food manufacturing, processing, packing, or holding . . . .'' The verification procedures discussed in this section (i.e., environmental and product testing programs), when implemented appropriately in particular facilities, could be used to verify that the preventive controls are effectively and significantly minimizing or preventing the occurrence of identified hazards. The use of and need for these preventive controls and verification measures, which are science-based, are widespread and commonly accepted in many sectors of the food industry. The Agency requests comment on these conclusions.

As discussed (see section I of this document), animal food safety is best assured if each facility understands the hazards that are reasonably likely to occur in its particular product and operation and puts in place scientifically sound preventive controls to significantly minimize or eliminate those hazards. From a regulatory perspective, specifying the circumstances and manner in which these controls and practices are to be applied must take into account the wide array of factors, including the diversity among animal food products, the wide variety of manufacturing and processing methods used to produce the animal food, the variety of sources for raw materials and ingredients, variations in the nature and types of hazards associated with manufacturing, processing, packing, and holding animal food, and the possibility that different mitigation methods may achieve the same end. Further, regulatory requirements should make clear when one of these preventive controls or verification measures is necessary yet also be sufficiently flexible to account for a vast number of animal food and facility combinations and circumstances.

Although the Agency is not including provisions for environmental and product testing programs or a supplier approval and verification program in this proposed rule, the Agency recognizes that these preventive controls and verification measures, when implemented appropriately in particular facilities, can play important roles in effective animal food safety programs. The role and need for these measures varies depending on the type of products and activities of the facility. To facilitate comment and share the Agency's current thinking, the Agency discusses the topics of environmental and product testing programs and a supplier approval and verification program immediately below. See the Appendix to this document for additional background information relevant to these topics.

2. Product Testing

As discussed in section X.G.1, section 418(f)(4) of the FD&C Act states that the owner, operator, or agent in charge of a facility shall verify that ''the preventive controls implemented under [section 418(c) of the FD&C Act] are effectively and significantly minimizing or preventing the occurrence of identified hazards, including through the use of environmental and product testing programs and other appropriate means'' The statute does not indicate the specific circumstances where product testing would be required or the specific manner in which such testing should be performed. FDA believes that the role and need for these measures varies depending on the type of products and activities of a facility. FDA further believes that the owner, operator, or agent in charge of a facility could consider a number of factors to establish a product testing program.

Although finished product testing is rarely considered a preventive control, it plays a very important role as a verification measure in ensuring the safety of animal food, when implemented appropriately in particular facilities. Similarly, testing of raw materials or ingredients by a facility that is receiving the product often plays an important role in verification of hazard control that is performed by its supplier. Thus, an important purpose of testing is to verify that preventive controls, including those related to suppliers and those related to environmental monitoring, are controlling the hazard (Refs. 31 and 32). Testing is used in conjunction with other verification measures in the animal food safety system, such as audits of suppliers, observations of whether activities are being conducted according to the food safety plan, and reviewing records to determine whether process controls are meeting specified limits for parameters established in the food safety plan.

Finished product testing is more important and useful when there is a reasonable probability that exposure to an identified hazard will result in serious adverse health consequences or death to humans or animals. FDA believes that there are certain situations in which finished product testing is particularly useful as a verification measure, including the following circumstances:

- The outcome of the hazard analysis conducted under proposed § 507.33 is that a biological hazard is reasonably likely to occur in an ingredient and the preventive controls established and implemented under proposed § 507.36 do not include a process control that will significantly minimize the hazard. An example is a dry blending operation that mixes a variety of ingredients such as seeds, nuts that may be contaminated with *Salmonella* spp., dried fruit, and algae meal to make bird food.
- The outcome of the hazard analysis conducted under proposed § 507.33 is that a biological hazard is reasonably likely to occur in an ingredient that is added during manufacturing after the stage that applies a process control to significantly minimize biological hazards. An example is pet food (such as dry pet food and pet treats) in which untreated flavorings that may contain *Salmonella* spp. are applied after the pet food has undergone a heat treatment.
- The outcome of the hazard analysis conducted under proposed § 507.33 is that a biological hazard is reasonably likely to occur as a result of handling of a product or exposure of a product to the environment after a process control that significantly minimizes a hazard such that a hazard could be introduced or re-introduced into the product. An example is the manufacture of pet treats, such as pig ears, that after heat treating become contaminated with *Salmonella* spp. from the processing environment.

In addition, the frequency of testing and the number of samples tested must be determined and needs to take into account a variety of hazard/commodity/facility considerations. FDA believes that factors to consider include whether ingredients that may contain a hazard have been tested, the extent of any environmental monitoring program, and whether other programs established by the facility provide added assurance that the potential for hazards has been minimized. The frequency of testing and the number of samples tested should have a scientific basis. Sampling plans and their performance have been described in the literature (Refs. 89, 90, and 91) and are included in several Codex documents (Refs. 92 and 93). The Agency discusses likely considerations that could impact finished product verification testing in more detail in section I.F of the Appendix.

Although the Agency is not including a testing provision in this proposed rule, the Agency estimates that a requirement for a finished product testing program, when implemented appropriately in particular facilities, could impose an incremental annual cost of $15,000–$28,000 per facility based on size (number of employees) that adopts a testing and holding regime. This would result in an estimated aggregate cost of $2.88 million, of which about 73 percent would be for domestic facilities. The facilities that would adopt a testing and holding regime are facilities producing products for which finished product testing would be particularly useful as a verification measure, e.g., the production process does not have a step that will eliminate or reduce hazards to an acceptable level. This estimate excludes facilities that would be exempt under this proposed rule (using a definition of $500,000 for a very small business) and facilities that are already conducting finished product testing. Further details are provided in the ''Analysis of Alternatives'' section of FDA's Preliminary Regulatory Impact Analysis (PRIA) (Ref. 52).

FDA requests comment on when and how product testing programs are an appropriate means of implementing the statutory directives set out above. Although the Agency has not included these provisions in the proposed rule, the Agency requests comment on their inclusion in a final rule. Should a product testing program be limited to finished product testing or include raw material testing? What is the appropriate level of specificity for a product testing program? For example, should the Agency simply require that the owner, operator, or agent in charge conduct, as appropriate to the facility and the animal food, finished product testing, when appropriate based on risk, to assess whether the preventive controls significantly minimize or prevent the hazards that are reasonably likely to occur? This would provide flexibility to account for the wide diversity of animal food and animal food manufacturing, processing, packing, and holding systems subject to this rule and be consistent with the discussions within this proposed rule.

FDA also requests comment on whether more detail would be appropriate, by, for example:

- Specifying particular hazards, situations or product types for which finished product testing would be required;
- Specifying the frequency of testing and, if so, whether this frequency should depend on the type of product;
- Identifying appropriate sampling plans for finished product testing;
- Requiring periodic testing for trend analysis and statistical process control; and
- Requiring written procedures for conducting finished product testing and, if so, also require that procedures for finished product testing be scientifically valid and include the procedures for sampling and the sampling frequency.

FDA also requests comment on the impact of product testing requirements on small businesses and on whether any product testing verification requirements should differ based on the size of the operation.

3. Environmental Monitoring

As discussed in section X.G.1 of this document, section 418(f)(4) of the FD&C Act states that the owner, operator, or agent in charge of a facility shall verify that ''the preventive controls implemented under [section 418(c) of the FD&C Act] are effectively and significantly minimizing or preventing the occurrence of identified hazards, including through the use of environmental and product testing programs and other appropriate means.'' In addition, section 418(o)(3) indicates that preventive controls may include environmental monitoring to verify the effectiveness of pathogen controls is an example of preventive controls. The statute does not indicate the specific circumstances where environmental testing would be required or the specific manner in which such testing should be performed. Nevertheless, FDA believes that this testing can form an important component of a modern animal food safety system. FDA believes that the role and need for these measures varies depending on the type of products and activities of a facility. FDA further believes that the performance of environmental monitoring, for an appropriate microorganism of public health significance or for an appropriate indicator organism, is particularly useful as a verification measure for preventive controls (i.e., sanitation controls) when contamination of animal food with an environmental pathogen is a hazard reasonably likely to occur.

As discussed in section X.B.3, proposed § 507.33(b) would require a hazard identification that must consider hazards that may occur naturally or may be unintentionally introduced. The data from recalls and the RFR support a conclusion that *Salmonella* spp. is a hazard in animal pet treats and pet food products. When certain animal food, such as dry pet food, is exposed to the environment prior to packaging, FDA believes that most facilities producing such animal foods would identify *Salmonella* spp. as a known or reasonably foreseeable hazard under proposed § 507.33(b). A robust environmental monitoring program for *Salmonella* spp. can verify the effectiveness of sanitation controls designed to prevent *Salmonella* spp. from contaminating animal food-contact surfaces and animal food (Ref. 94).

As discussed in section I.E.2 of the Appendix to this document, the Agency is also aware that listeriosis occurs in a number of animal species, especially ruminant animals, and is asking for comment on whether *L. monocytogenes* is an environmental pathogen of concern for animal food facilities. FDA's current thinking is that *Listeria* spp. may be an appropriate indicator organism for *L. monocytogenes,* because tests for *Listeria* spp. will detect multiple species of *Listeria,* including *L. monocytogenes.* However, FDA's current thinking is that there are no currently available indicator organisms for *Salmonella* spp. The Agency requests comment on these findings and conclusions.

Although the Agency is not including an environmental testing provision in this proposed rule, the Agency estimates that an environmental monitoring program for *Salmonella* spp., when implemented appropriately in certain animal food facilities, could impose an annual cost of about $3,500 per facility. These costs assume that facilities will collect approximately 15 environmental samples per month, based on facility size. FDA used the sampling time, testing time, and capital cost to estimate a cost of $19.20 per sample tested using a quick time test that is performed at the facility. FDA estimates that about 261 facilities (including foreign facilities) would be subject to this requirement. FDA used the current compliance estimates from the human foods manufacturer survey to estimate the total that would need to begin environmental monitoring would be about 184. This would result in estimated total annual testing costs of about $636,000.

The facilities that could adopt environmental monitoring programs are facilities producing animal food products, such as dry pet food, exposed to the environment prior to packaging, whereby they may become contaminated and for which such testing would be particularly useful as a verification measure for sanitation controls.

FDA requests comment on when and how environmental testing is an appropriate means of implementing the statutory directives set out above. Although the Agency has not included these provisions in the proposed rule, the Agency requests comment on their inclusion in a final rule. If they are included, what is the appropriate level of specificity? For example, should the Agency simply require the performance of environmental monitoring, for an appropriate microorganism of public health significance or for an appropriate indicator organism, if contamination of animal food with an environmental pathogen is a hazard reasonably likely to occur? FDA also requests comment on whether more detail would be appropriate, by, for example:

- Specifying the environmental pathogen or the indicator organism for which the samples must be tested;
- Specifying the corrective actions that should be taken if environmental testing identifies the presence of an environmental pathogen, such as;
- Conducting microbial sampling and testing of surrounding surfaces and areas to determine the extent of the contamination and the potential source of the contamination;
- Cleaning and sanitizing the contaminated surfaces and surrounding areas to eliminate the test organism;
- Conducting additional microbial sampling and testing to determine whether the contamination has been eliminated; and
- Conducting finished product testing.
- Specifying the locations within the facility at which samples must be collected;
- Specifying the frequency of collection of environmental samples (e.g., weekly or monthly depending on risk). For example, should the frequency of collection:
- Be greatest for animal foods that are likely to be handled by certain vulnerable populations, such as children, the elderly, and individuals with compromised immune systems after a minimal treatment that may not adequately reduce the environmental pathogen?
- Be greater for an environmental pathogen that is frequently introduced into a facility (e.g., *Salmonella* spp., which is ubiquitous in the environment and can be continually introduced into a facility from many routes, including ingredients, people and objects (Ref. 94)) than for an environmental pathogen that is less frequently introduced?
- Be greater for products that undergo significant handling and exposure to the environment than for products that undergo limited or no handling or have little exposure to the environment?
- Increase as a result of finding the environmental pathogen or an indicator of the environmental pathogen or as a result of situations that pose an increased risk of contamination, e.g., construction? (Refs. 94 and 95).
- Requiring written procedures for conducting environmental testing and, if so, also requiring that procedures for environmental testing be scientifically valid and include the procedures for sampling and the sampling frequency;
- Requiring data analysis to detect trends.

The Agency further requests comment on whether there is benefit in conducting routine environmental monitoring for other organisms in addition to, or instead of, the environmental pathogen of concern.

4. Supplier Approval and Verification Program

Section 418(c) of the FD&C Act specifies, in relevant part, that the owner, operator, or agent in charge of a facility shall identify and implement preventive controls, including at critical control points, if any, to provide assurances that:

- Hazards identified in the hazard analysis conducted under section 418(b)(1) of the FD&C Act will be significantly minimized or prevented; and
- The animal food manufactured, processed, packed, or held by such facility will not be adulterated under section 402 of the FD&C Act.

Section 418(o)(3)(G) of the FD&C Act indicates that the procedures, practices, and processes described in the definition of preventive controls may include supplier verification activities that relate to the safety of food. While FSMA refers only to supplier verification activities, supplier approval, together with supplier verification, is widely accepted in the domestic and international food safety community. The development of a supplier approval and verification program can be part of a preventive approach. The NACMCF HACCP guidelines describe supplier controls as one of the common prerequisite programs for the safe production of food products and recommend that each facility assure that its suppliers have in place effective CGMP and food safety programs (Ref. 29). Likewise, Codex addresses the safety of ingredients in the General Principles of Food Hygiene and recommends that, where appropriate, specifications for raw materials be identified and applied and laboratory tests be conducted to establish fitness for use (Ref. 34).

Because many facilities acting as suppliers procure their raw materials and ingredients from other suppliers, there is often a chain of suppliers before a raw material or other ingredient reaches the manufacturer/processor. Using a preventive approach, a facility receiving raw materials or ingredients from a supplier can help ensure that the supplier (or a supplier to the supplier) has implemented preventive controls to significantly minimize or prevent hazards that the receiving facility has identified as reasonably likely to occur in that raw material or other ingredient unless the receiving facility will itself control the identified hazard.

A supplier approval and verification program can help ensure that raw materials and ingredients are procured from those suppliers that can meet company specifications and have appropriate programs in place to address the safety of the raw materials and ingredients. A supplier approval program can ensure a methodical approach to identifying such suppliers. A supplier verification program can help provide initial and ongoing assurance that suppliers are complying with practices to achieve adequate control of hazards in raw materials or ingredients.

The statute does not indicate the specific circumstances where supplier verification would be required or the specific manner in which supplier verification should be performed, and FDA is not including provisions for such verification in this proposed rule. FDA believes that the role and need for these measures varies depending on the type of products and activities of a facility. FDA further believes that the owner, operator, or agent in charge of a facility could consider a number of factors to determine the specific circumstances and manner where it would be appropriate to perform supplier verification. FDA believes that factors to consider include:

- The nature of the adverse consequences associated with the hazard, such as whether consumption or handling of animal food containing the hazard may result in serious adverse health consequences or death to humans or animals; and
- The establishment that would be controlling the hazard associated with the raw material or ingredient (e.g., the facility that receives the raw material or ingredient, the supplier of that raw material or ingredient, or even a supplier to the supplier of the raw material or ingredient).

The vast majority of costs related to a supplier approval and verification program are due to verification activities such as audits and testing of raw materials and ingredients, which would likely be selected based on the hazard associated with the raw material or ingredient and where the hazard is controlled. Although the Agency is not including a provision for such a program in this proposed rule, the Agency estimates that a requirement for a supplier approval and verification program, if implemented as part of a preventive approach, could impose an incremental annual cost of $3,300–$4,400 per supplier facility based on size (number of employees) that undergoes an annual audit. This would result in an estimated aggregate cost of $218,000 for domestic facilities and an estimated aggregate cost of $82,000 for foreign facilities. Further details are provided in the ''Analysis of Alternatives'' section of the PRIA (Ref. 52).

FDA requests comment on when and how supplier approval and verification is an appropriate means of implementing the statutory directives set out previously. Although the Agency has not included these provisions in the proposed rule, the Agency requests comment on their inclusion in a final rule. If they are included, what is the appropriate level of specificity? Should the requirement be very general, for example, requiring a supplier approval and verification program as appropriate to the facility and the animal food, when appropriate based on risk? FDA also requests comment on who a supplier approval and verification program should apply to, e.g., should it apply to all facilities that manufacture, process, pack, or hold animal food, or be limited (such as to facilities that manufacture or process animal food)?

FDA also requests comment on whether more detail would be appropriate, by, for example:

- Requiring that the supplier approval and verification program include a written list of approved suppliers;
- Requiring that, in determining appropriate verification activities, the owner, operator, or agent in charge of a facility consider relevant regulatory information regarding the supplier, including whether the raw material or ingredient is the subject of an FDA warning letter or import alert relating to the safety of the animal food.
- Specifying circumstances when a supplier approval and verification program would not be required, e.g., when the preventive controls at the receiving facility are adequate to significantly minimize or prevent each of the hazards the receiving facility has identified as reasonably likely to occur; or when the receiving facility obtains from its customer written assurance that the customer has established and is following procedures that will significantly minimize or prevent the hazard.
- Specifying that the type of verification activity be linked to the seriousness of the hazard, e.g., whether to:
- Require an onsite audit when there is a reasonable probability that exposure to the hazard will result in serious adverse health consequences or death to humans or animals;
- Provide more flexibility with respect to hazards for which there is not a reasonable probability that exposure to the hazard will result in serious adverse health consequences or death to humans or animals, e.g., periodic onsite audits, periodic or lot-by-lot sampling and testing of the raw material or ingredient, and periodic review of the supplier's animal food safety records;
- Specifying requirements for audits, e.g., the qualifications (including training, experience, and conflict of interest) for persons who conduct audits; content of an audit (such as compliance with applicable animal food safety regulations and, when applicable, compliance with a facility's food safety plan);
- Specifying the frequency of verification activities (e.g., initially, annually, or periodically);
- Specifying whether, for some hazards, it will be necessary to conduct more than one verification activity to provide adequate assurances that the hazard is significantly minimized or prevented;
- Providing for alternative requirements if a supplier is a qualified facility, e.g., documenting that the supplier is a qualified facility and obtaining written assurance that the supplier is producing the raw material or ingredient in compliance with sections 402 of the FD&C Act;
- Specifying those records that would be appropriate for a supplier approval and verification program;
- Providing for substitution of a regulatory inspection (e.g., by FDA or a comparable State regulatory agency or foreign animal food safety authority), for an onsite audit; and
- Specifying that a receiving facility take appropriate action (e.g., discontinuing use of a supplier) if the facility determines that the supplier is not controlling hazards that the receiving facility has identified as reasonably likely to occur.

FDA is aware that many firms that could be affected by supplier verification may be importing their ingredients. The Agency believes that these firms are interested in how a supplier verification component of preventive controls will interface with the regulations FDA is required to implement foreign supplier verification under new section 805 of the FD&C Act (21 U.S.C. 384a). Section 805 requires FDA to issue regulations to require importers to implement foreign supplier verification programs (FSVPs) that are adequate to provide assurances that the importer's foreign suppliers produce food, including animal food, in compliance with processes and procedures, including risk-based preventive controls, that provide the same level of animal and human health protection as those required under section 418 (concerning hazard analysis and preventive controls) of the FD&C Act, and in compliance with section 402 (concerning adulteration) of the FD&C Act.

On July 29, 2013, FDA published in the **Federal Register** proposed regulations implementing section 805 (78 FR 45730). FDA intends to align regulations implementing supplier verification under section 418 and regulations implementing FSVP under section 805 to the fullest extent so the Agency does not impose duplicative or unjustified requirements under those two regulations. For example, if a facility imports ingredients, the Agency would not want to subject it to duplicative requirements under a supplier verification provision and an FSVP regulation.

Likewise, FDA is aware that there is great interest from its trading partners on, among other things, the potential overlap between the supplier verification requirements in preventive controls and in FSVP. FDA believes that the approach to harmonization between supplier verification and FSVP described above would adequately address this and comports with its obligations under the World Trade Organization trade agreements, including adherence to the principles of the Sanitary and Phytosanitary (SPS) Agreement.

FDA is committed to meeting the requirements of the SPS Agreement and to complying with its obligations under that Agreement as the Agency implements FSMA. In enacting FSMA, Congress explicitly recognized the importance of compliance with international agreements by providing in section 404 of FSMA that ''[n]othing in [FSMA] shall be construed in a manner inconsistent with the agreement establishing the World Trade Organization or any other treaty or international agreement to which the United States is a party.'' While the statutory provisions in FSMA governing supplier verification by domestic facilities and foreign supplier verification by importers differ in some respects, they are based on common risk-based principles. Implementation of these risk-based principles will assure a general consistency of approach with respect to foreign and domestic facilities regarding, for example, when on-site audits are required. Implementation of FSMA's risk-based principles will also ensure that measures applicable to imports are not more trade-restrictive than required to achieve the appropriate level of sanitary or phytosanitary protection of the United States, taking into account technical and economic feasibility, as required by paragraph 6 of Article 5 of the SPS Agreement. The Agency invites comments to assist it in issuing final rules that protect animal and human health and satisfy both FSMA and FDA's international obligations.

L. Request for Comment on Other Potential Provisions Not Explicitly Included in Section 418 of the FD&C Act

1. Overview

This section discusses two measures (review of consumer, customer, and other complaints, and submission of a food safety profile) that FDA is not proposing as specific provisions in proposed part 507, subpart C. Although these measures are not explicitly included in section 418, the Agency believes that the preventive controls and verification measures discussed in this section are an important part of a modern food safety system.

2. Complaints

The role of consumer complaints in evaluating the effectiveness of a food safety plan is reflected in the HACCP regulations for seafood and juice. The HACCP regulation for seafood (§ 123.8(a)(2)(i)) requires that verification activities include a review of any consumer complaints that have been received by the processor to determine whether they relate to the performance of critical control points or reveal the existence of unidentified critical control points. The HACCP regulation for juice (§ 120.11(a)(1)(i)) requires that verification activities include a review of any consumer complaints that have been received by the processor to determine whether the complaints relate to the performance of the HACCP plan or reveal the existence of unidentified critical control points. FDA notes that the role of consumer complaints is not discussed in the NACMCF guidelines or the Codex guidelines, and their review is not required by the FSIS HACCP regulation for meat and poultry. However, as discussed in the seafood HACCP proposed rule (59 FR 4142 at 4157, January 28, 1994), no system is foolproof, and consumer complaints may be the first alert for a processor that deviations are occurring and are not being prevented or uncovered by the processor's HACCP controls.

Further, although most consumer complaints will be related to quality issues, recent experience has demonstrated the value that consumer and customer complaints can provide in bringing attention to possible problems within a facility's preventive controls activities. FDA has received a number of animal food submissions to the RFR (Ref. 48) that have suggested that environmental pathogens hazards were not adequately addressed in a supplier's food safety plan. Some of these were identified through customer verification testing and others through complaints from consumers to a facility. A facility may also receive alerts as a result of state surveillance and testing programs.

Although this proposed rule does not include a provision regarding a review of complaints, the Agency estimates that a requirement that facility personnel review consumer, customer, or other complaints could impose an additional annual cost of $2,800 per facility. This would result in an estimated total annual cost of $1,767,000 for domestic facilities.

The Agency requests comment on whether and how a facility's review of complaints, including complaints from consumers, customers, or other parties, should be required as a component of its activities to verify that its preventive controls are effectively minimizing the occurrence of hazards.

3. Submission of a Facility Profile to FDA

Proposed § 507.30 would require that the owner, operator, or agent in charge of a facility prepare, or have prepared, a written food safety plan. The food safety plan would include the hazard analysis, preventive controls, and other records. Currently, information of this type is not reviewed by FDA investigators until they are physically present at a facility and have begun an inspection. In light of the large number of facilities that would be covered by this proposal, FDA recognizes several potential benefits to having a facility's food safety plan in advance of an inspection, if the Agency were to require facilities to do so. Having such plans could aid in the efficient oversight of preventive controls by allowing FDA to better target inspectional activities to facilities that produce animal foods that have an increased potential for contamination (particularly with biological hazards) and to improve on-site inspections by focusing attention on hazards and preventive controls for which the facility appears to have deficiencies. Facilities would benefit from the Agency's advance preparation through interaction with better-informed investigators and potentially reduced inspection time. The Agency could also more quickly identify facilities that had not established preventive controls for specific hazards of concern to the Agency and advise them to fill such gaps to prevent a problem before it occurs. Also, FDA could use the plans in evaluating the need for guidance on specific hazards or controls and prioritizing guidance to areas where it is needed most.

FDA believes that there are significant obstacles to realizing these benefits from submission of food safety plans, however. The agency would expect to receive a very large number of plans. Further, these plans would be expected to vary significantly in content and format. Assimilating the underlying information in a way that would be useful to the Agency would be an immense challenge. Moreover, not all of the information in such plans may be essential to realizing the potential benefits described above. Therefore, to most efficiently realize the potential benefits of having certain information prior to an inspection, the Agency requests comment on whether to require submission to FDA of a subset of the information that would be in a food safety plan. This information, which could be referred to as a "facility profile," could be submitted through an electronic form using a menu selection approach. The use of an electronic form would enhance the Agency's ability to store the information in a searchable form. Ideally, a searchable electronic system could allow FDA to assess information when a problem occurs with certain types of foods or controls, so that the Agency could target inspections to facilities that manufacture, process, or pack, animal food types that are at increased risk for a food safety problem; to facilities that appear to have insufficient controls to prevent a problem; or to facilities using a control the Agency concludes is ineffective at controlling hazards. The data elements for a facility profile could include some or all of the following:

- Contact information;
- Facility type;
- Products;
- Hazards identified for each product;
- Preventive controls established for each of the identified hazards;
- Third-party audit information (have you had one and which audit firm(s));
- Preventive control employee training conducted;
- Facility size (square footage);
- Full time operation or seasonal;
- Operations schedule.

This information could be submitted at the same time as facility registration and updated biennially simultaneously with the required biennial update of the food facility registration. FDA requests comment on the utility and necessity of such an approach and on the specific types of information that would be useful in developing a facility profile. The Agency also requests comment on any additional benefits that might be obtained from using such an approach and any potential concerns with this approach.

The Agency has previously announced an opportunity for public comment on the proposed collection of additional food facility profile information on a voluntary basis from firms that complete the FDA food facility registration process (77 FR 27779, May 11, 2012). In that notice, the Agency noted that FSMA added section 421 of the FD&C Act (21 U.S.C. 350j), which directed FDA to allocate resources to inspect facilities according to the known safety risks of the facilities. The Agency also noted that food facility profile information voluntarily provided to FDA would help FDA to determine whether a firm is high-risk or non-high-risk and that the Agency will use the profile information to assist in determining the frequency at which it will inspect the firm. In contrast to the voluntary submission of food facility profile information described in that notice, in this document, the Agency is also requesting comment on whether the submission of such information should be required.

XI. Proposed Subpart D—Withdrawal of an Exemption Applicable to a Qualified Facility

A. Requirements of Section 418 of the FD&C Act

Section 418(l)(3)(A) of the FD&C Act specifies that, in the event of an active investigation of a foodborne illness outbreak that is directly linked to a qualified facility subject to an exemption under section 418(l) of the FD&C Act, or if the Secretary determines that it is necessary to protect the public health and prevent or mitigate a foodborne illness outbreak based on conduct or conditions associated with a qualified facility that are material to the safety of the food manufactured, processed, packed, or held at such facility, the Secretary may withdraw the exemption provided to such facility under section 418(l) of the FD&C Act. Section 418 does not expressly prescribe the procedures for withdrawing an exemption provided to a qualified facility under section 418(l). The Agency tentatively concludes that it is appropriate to be transparent about the process it would use to withdraw an exemption and that the Agency should include the process in the proposed rule.

B. Proposed § 507.60—Circumstances That May Lead FDA To Withdraw an Exemption Applicable to a Qualified Facility

1. Proposed § 507.60(a)—Withdrawal of an Exemption in the Event of an Active Investigation of a Foodborne Illness Outbreak

Proposed § 507.60(a) would provide that FDA may withdraw the exemption that would be applicable to a qualified facility under proposed § 507.5(c) in the event of an active investigation of a foodborne illness outbreak that is directly linked to the qualified facility. Proposed § 507.60(a) would implement the statutory language of section 418(l)(3)(A) of the FD&C Act. An outbreak of foodborne illness is the occurrence of two or more cases of a similar illness resulting from the ingestion of a common food (or exposure to a common food in the case of microbiological illness in humans from handling animal food.) Animal food can become contaminated at many different steps: On the farm; in packing, manufacturing/processing, or distribution facilities; during storage or transit; at retail establishments; and at the location of the animal. When foodborne illness is associated with food, a traceback investigation may enable FDA to directly link the illness to the facility or facilities that manufactured, processed, packed, and/or held the animal food. See section XIV.B.1 of the document for the proposed rule for preventive controls for human food (78 FR 3646) for a discussion of an FDA traceback investigation.

2. Proposed § 507.60(b)—Withdrawal of an Exemption Based on Conduct or Conditions Associated With a Qualified Facility

Proposed § 507.60(b) would provide that FDA may withdraw the exemption applicable to a qualified facility under proposed § 507.5(c) if FDA determines that it is necessary to protect animal or human health and prevent or mitigate a foodborne illness outbreak based on conduct or conditions associated with a qualified facility that are material to the safety of the animal food manufactured, processed, packed, or held at such facility. As an example, FDA may receive reports to the RFR under section 417 of the FD&C Act about contamination of an animal food, and the reports may lead the Agency to investigate a qualified facility that manufactured, processed, packed or held the animal food. If the investigation finds conduct or conditions associated with the facility that are material to the safety of the animal food (for example, conduct or conditions that likely led to the contamination of the animal food), FDA would consider withdrawing the exemption applicable to the facility under proposed § 507.5(c) if doing so would be necessary to protect animal or human health and prevent or mitigate a foodborne illness outbreak. Likewise, if during a routine inspection of a qualified facility, FDA discovers conditions and practices that are likely to lead to contamination of animal food with microorganisms of animal or human health significance, such as *Salmonella,* the Agency would consider withdrawing the exemption provided to the facility under proposed § 507.5(c) if doing so would be necessary to protect animal or human health and prevent or mitigate a foodborne illness outbreak.

C. Proposed § 507.62—Issuance of an Order To Withdraw an Exemption Applicable to a Qualified Facility

Proposed § 507.62(a) would provide that, if FDA determines that an exemption applicable to a qualified facility under § 507.5(c) should be withdrawn, any officer or qualified employee of FDA may issue an order to withdraw the exemption. The Agency intends to create and maintain a written record of a determination that the withdrawal of an exemption is warranted and to include the basis for the determination in the written record.

Proposed § 507.62(b) would require that an FDA District Director in whose district the qualified facility is located (or, in the case of a foreign facility, the Director of the Division of Compliance in the Center for Veterinary Medicine), or an FDA official senior to such Director, must approve an order to withdraw the exemption as part of the withdrawal determination procedure before the order is issued. A Regional Food and Drug Director is an example of an FDA official senior to a District Director. The Deputy Director and Director of the Office of Surveillance and Compliance at the Center for Veterinary Medicine are examples of an FDA official senior to the Director of the Division of Compliance. Requiring prior approval of a withdrawal order by a District Director or an FDA official senior to a District Director is consistent with the approval requirement for a detention order in part 1, subpart K

(Administrative Detention of Food for Human or Animal Consumption). Requiring prior approval of a withdrawal order by the Director of the Division of Compliance in the Center for Veterinary Medicine is consistent with current FDA practices when dealing with foreign firms.

Proposed § 507.62(c) would require that FDA issue an order to withdraw the exemption to the owner, operator, or agent in charge of the qualified facility. The requirements of section 418 of the FD&C Act are directed to the owner, operator, or agent in charge of a facility. The Agency tentatively concludes that the statutory language of section 418 enables FDA to issue an exemption withdrawal order to any of these persons.

Proposed § 507.62(d) would require that FDA issue an order to withdraw the exemption in writing, signed and dated by the officer or qualified employee of FDA who is issuing the order.

D. Proposed 507.65—Contents of an Order To Withdraw an Exemption Applicable to a Qualified Facility

Proposed § 507.65(a) through (i) would require that an order to withdraw an exemption applicable to a qualified facility under § 507.5(c) include the following information:

- The date of the order (proposed § 507.65(a));
- The name, address, and location of the qualified facility (proposed § 507.65(b));
- A brief, general statement of the reasons for the order, including information relevant to:
  - ○ An active investigation of a foodborne illness outbreak that is directly linked to the facility; or
  - ○ Conduct or conditions associated with a qualified facility that are material to the safety of the animal food manufactured, processed, packed, or held at such facility (proposed § 507.65(c)).
- A statement that the facility must comply with subpart C of this part on the date that is 60 calendar days after the date of the order (proposed § 507.65(d));
- The text of section 418(l) of the FD&C Act and of this subpart D (proposed § 507.65(e));
- A statement that any informal hearing on an appeal of the order must be conducted as a regulatory hearing under part 16 of this chapter (21 CFR part 16), with certain exceptions described in proposed § 507.73 (proposed § 507.65(f));
- The mailing address, telephone number, email address, and facsimile number of the FDA district office and the name of the FDA District Director in whose district the facility is located (or, in the case of a foreign facility, the same information for the Director of the Division of Compliance in the Center for Veterinary Medicine); (proposed § 507.65(g)); and
- The name and the title of the FDA representative who approved the order (proposed § 507.65(h)).

FDA tentatively concludes that the requirements that it proposes in § 507.65 would provide the owner, operator, or agent in charge of a qualified facility subject to a withdrawal with adequate notice of the basis for the Agency's determination to withdraw the exemption and of their opportunity to appeal the Agency's determination and to request an informal hearing. The proposed notification procedures are similar to and consistent with the notification requirements in other regulations involving administrative action, such as administrative detention of food under § 1.393 orders for diversion or destruction of shell eggs under the PHS Act under § 118.12(a)(i), and with procedures for an informal hearing in part 16.

E. Proposed § 507.67—Compliance With, or Appeal of, an Order To Withdraw an Exemption Applicable to a Qualified Facility

Proposed § 507.67(a) would require that the owner, operator, or agent in charge of a qualified facility that receives an order to withdraw an exemption applicable to that facility under § 507.5(c) either comply with applicable requirements of this part within 60 calendar days of the date of the order; or appeal the order within 10 calendar days of the date of the order in accordance with the requirements of § 507.69. The Agency tentatively concludes that either of the two circumstances that could result in the determination that an exemption should be withdrawn (as described in proposed § 507.60) warrant prompt compliance with the rule in the interest of animal or human health. The Agency tentatively concludes that 10 calendar days for the submission of an appeal from the date of the receipt of a withdrawal order is appropriate for purposes of the efficient adjudication of the appeal of a withdrawal order and would provide reasonable due process that comes to closure sufficiently in advance of the effective date of the order to provide an opportunity for the facility to come into compliance if the Agency denies the appeal.

Proposed § 507.67(b) would establish that submission of an appeal, including submission of a request for an informal hearing, will not delay or stay any administrative action, including enforcement action by FDA, unless the Commissioner of Food and Drugs, as a matter of discretion, determines that delay or a stay is in the public interest. For example, the submission of an appeal of a withdrawal order with a request for an informal hearing under proposed § 507.67(b) would not prevent FDA from simultaneously detaining animal food from the facility under section 304(h) of the FD&C Act, seizing animal food from the facility under section 304(a) of the FD&C Act, or seeking or enforcing an injunction under section 302 of the FD&C Act.

Proposed § 507.67(c) would require that, if the owner, operator, or agent in charge of the qualified facility appeals the order, and FDA confirms the order, the owner, operator, or agent in charge of the facility must comply with applicable requirements of this part within 60 calendar days of the date of the order. Proposed § 507.67(c) would make clear that the 60 calendar day timeframe for compliance applies regardless of whether the owner, operator, or agent in charge of a facility requests, and FDA grants, a hearing. As already discussed, FDA tentatively concludes that the circumstances that lead to a determination that an exemption should be withdrawn warrant prompt compliance in the interest of animal or human health.

F. Proposed § 507.69—Procedure for Submitting an Appeal

Proposed § 507.69(a) would require that, to appeal an order to withdraw an exemption applicable to a qualified facility under § 507.5(c), the owner, operator, or agent in charge of the facility must: (1) Submit the appeal in writing to the FDA District Director in whose district the facility is located (or, in the case of a foreign facility, the same information for the Director of the Division of Compliance in the Center for Veterinary Medicine), at the mailing address, email address, or facsimile number identified in the order within 10 calendar days of the date of the order and (2) respond with particularity to the facts and issues contained in the order, including any supporting documentation upon which the owner, operator or agent in charge of the facility relies.

Allowing the owner, operator, or agent in charge of the facility to submit an appeal in person, by mail, email, or fax would provide for flexibility as well as speed. For example, submitting in person would give the owner, operator, or agent in charge direct knowledge that the request for appeal had been delivered and received. Email and fax are instantaneous, and overnight mail delivery services are readily available to those who choose to use them; however, the 10 day timeframe for appeal of the order would not require the use of overnight mail delivery. For clarity, proposed § 507.69(a) would repeat the 10 calendar day timeframe that would be established in proposed § 507.67(a)(2) and would not establish any new requirement. Any appeal would need to be written in order for FDA to evaluate the basis for the appeal. The Agency is proposing that a written appeal would need to address with particularity all of the issues raised in the withdrawal order and include all supporting documentation so that the Agency would be able to issue a final determination as to the disposition of the appeal solely on the basis of the materials submitted as part of the written appeal.

Proposed § 507.69(b) would provide that, in a written appeal of the order withdrawing an exemption provided under § 507.5(c), the owner, operator, or agent in charge of the facility may include a written request for an informal hearing as provided in § 507.71. Requesting an informal hearing does not mean that a hearing will be held, because FDA may deny the request (see discussion of proposed § 507.71(b) in the next section of this document). However, if the owner, operator, or agent in charge of the facility does not request an informal hearing at the time the written appeal is submitted, the owner, operator, or agent in charge of the facility will not be entitled to an informal hearing. Instead, FDA will make a final decision based on the written appeal and its supporting materials.

G. Proposed § 507.71—Procedure for Requesting an Informal Hearing

Proposed § 507.71(a)(1) would provide that, if the owner, operator, or agent in charge of the facility appeals the order, the owner, operator, or agent in charge of the facility may request an informal hearing. Proposed § 507.71(a)(1) would restate an option that would be included in proposed § 507.69(b) to highlight the opportunity to request an informal hearing. Proposed § 507.71(a)(2) would require that, if the owner, operator, or agent in charge of the facility appeals the order, the owner, operator, or agent in charge of the facility must submit any request for an informal hearing together with its written appeal submitted in accordance with § 507.69 within 10 calendar days of the date of the order. The Agency tentatively concludes that requiring submission of a request for an informal hearing in writing at the time that the owner, operator, or agent in charge of the facility would be required to submit a written appeal is appropriate for purposes of the efficient adjudication of the appeal of a withdrawal order and would provide reasonable due process that would come to closure sufficiently in advance of the effective date of the order to provide an opportunity for the facility to come into compliance if FDA denies the appeal.

Proposed § 507.71(b) would establish that a request for an informal hearing may be denied, in whole or in part, if the presiding officer determines that no genuine and substantial issue of material fact has been raised by the material submitted. Proposed § 507.71(b) would also provide that if the presiding officer determines that a hearing is not justified, written notice of the determination will be given to the owner, operator, or agent in charge of the facility explaining the reason for the denial. Under proposed § 507.69(a), a written appeal would be required to respond with particularity to the facts and issues contained in the withdrawal order, including any supporting documentation upon which the owner, operator or agent in charge of the facility relies. If the materials submitted do not directly address the facts and issues contained in the withdrawal order in a manner that suggests that there is a dispute regarding the material facts contained in the order, the presiding officer may determine that an informal hearing is not warranted. The presiding officer may include written notice of the determination that a hearing is not justified as part of the final decision on the appeal.

H. Proposed § 507.73—Requirements Applicable to an Informal Hearing

Proposed § 507.73(a) would establish that, if the owner, operator or agent in charge of the facility requests an informal hearing, and FDA grants the request, the hearing will be held within 10 calendar days after the date the appeal is filed or, if applicable, within a timeframe agreed upon in writing by the owner, operator, or agent in charge of the facility and FDA. The Agency tentatively concludes that, if it grants a request for an informal hearing, holding the hearing within 10 calendar days, or within an alternative timeframe as agreed upon in writing, is appropriate for purposes of the efficient adjudication of the appeal of a withdrawal order and would provide reasonable due process that would come to closure sufficiently in advance of the effective date of the order to provide an opportunity for the facility to come into compliance if the Agency denies the appeal.

Proposed § 507.73(b) would establish that the presiding officer may require that a hearing conducted under this subpart E be completed within 1 calendar day, if appropriate. The Agency tentatively concludes that, if it grants a request for an informal hearing, limiting the time for the hearing itself to be completed within 1 calendar day is appropriate for purposes of the efficient adjudication of the appeal of a withdrawal order and would provide reasonable due process that would come to closure sufficiently in advance of the effective date of the order to provide an opportunity for the facility to come into compliance if the Agency denies the appeal.

Proposed § 507.73(c)(1) through (c)(7) would establish that, if the owner, operator or agent in charge of the facility requests an informal hearing, and FDA grants the request, FDA must conduct the hearing in accordance with part 16, except that:

- The order withdrawing an exemption under §§ 507.62 and 507.65, rather than the notice under § 16.22(a), provides notice of opportunity for a hearing under this section and is part of the administrative record of the regulatory hearing under § 16.80(a) of this chapter.
- A request for a hearing under this subpart D must be addressed to the FDA District Director (or, in the case of a foreign facility, the Director of the Division of Compliance in the Center for Veterinary Medicine) as provided in the order withdrawing an exemption.
- Section 507.75, rather than § 16.42(a), describes the FDA employees who preside at hearings under this subpart.
- Section 16.60(e) and (f) of this chapter does not apply to a hearing under this subpart. The presiding officer must prepare a written report of the hearing. All written material presented at the hearing will be attached to the report. The presiding officer must include as part of the report of the hearing a finding on the credibility of witnesses (other than expert witnesses) whenever credibility is a material issue, and must include a proposed decision, with a statement of reasons. The hearing participant may review and comment on the presiding officer's report within 2 calendar days of issuance of the report. The presiding officer will then issue the final decision.
- Section 16.80(a)(4) of this chapter does not apply to a regulatory hearing under this subpart. The presiding

officer's report of the hearing and any comments on the report by the hearing participant under § 507.73(c)(4) are part of the administrative record.

- No party shall have the right, under § 16.119 of this chapter to petition the Commissioner of Food and Drugs for reconsideration or a stay of the presiding officer's final decision.
- If FDA grants a request for an informal hearing on an appeal of an order withdrawing an exemption, the hearing must be conducted as a regulatory hearing under part 16, except that § 16.95(b) does not apply to a hearing under this subpart. With respect to a regulatory hearing under this subpart, the administrative record of the hearing specified in §§ 16.80(a)(1), (a)(2), (a)(3), and (a)(5), and 507.73(c)(5) constitutes the exclusive record for the presiding officer's final decision. For purposes of judicial review under § 10.45 (21 CFR 10.45), the record of the administrative proceeding consists of the record of the hearing and the presiding officer's final decision.

Under § 16.1(b), the procedures in part 16 apply when a regulation provides a person with an opportunity for a hearing on a regulatory action under part 16. Section 418 of the FD&C Act does not expressly provide for a hearing if circumstances lead FDA to determine that an exemption provided to a qualified facility under proposed § 507.5(c) should be withdrawn. However, the Agency tentatively concludes as a matter of agency discretion that providing an opportunity for a hearing by regulation in this subpart of the proposed rule would provide appropriate process to the owner, operator, or agent in charge of a qualified facility subject to withdrawal of the facility's exemption. The Agency also tentatively concludes that the modified part 16 procedures contained in this proposed rule would provide the owner, operator, or agent in charge of a qualified facility subject to a withdrawal order sufficient fairness and due process while enabling FDA to expeditiously adjudicate an appeal of a withdrawal order for which an informal hearing has been granted.

Section 16.119 provides that, after any final administrative action that is the subject of a hearing under part 16, any party may petition the Commissioner for reconsideration of any part or all of the decision or action under § 10.33 or may petition for a stay of the decision or action under § 10.35. Proposed § 507.73(c)(6) would specify that these procedures for reconsideration and stay would not apply to the process of withdrawing an exemption provided under proposed § 507.5(c). The circumstances that may lead FDA to withdraw an exemption include an active investigation of a foodborne illness outbreak that is directly linked to a qualified facility, or the Agency's determination that it is necessary to protect animal or human health and prevent or mitigate a foodborne illness outbreak based on conduct or conditions associated with a qualified facility that are material to the safety of the animal food manufactured, processed, packed, or held at such facility. Such circumstances require prompt action. Under § 16.120, a qualified facility that disagrees with FDA's decision to withdraw an exemption provided under § 507.5(c) has an opportunity for judicial review in accordance with § 10.45.

I. Proposed § 507.75—Presiding Officer for an Appeal and for an Informal Hearing

Proposed § 507.75 would require that the presiding officer for an appeal, and for an informal hearing, must be an FDA Regional Food and Drug Director or another FDA official senior to an FDA District Director. Under § 16.42(b), an officer presiding over an informal hearing is to be free from bias or prejudice and may not have participated in the investigation or action that is the subject of the hearing or be subordinate to a person, other than the Commissioner, who has participated in such investigation or action. An order for the withdrawal of an exemption applicable to a qualified facility must be approved by a District Director or an official senior to a District Director. It is therefore necessary that appeals of a decision to issue a withdrawal order should be handled by persons in positions senior to the District Directors. The Regional Food and Drug Director is such a person and could be from the same region where the facility is located, provided that the Regional Food and Drug Director did not participate in the determination that an exemption should be withdrawn and is otherwise free from bias or prejudice. Alternatively, the Regional Food and Drug Director could be from a different region than the region where the facility is located, for example in the event the Regional Food and Drug Director for the region in which the facility is located is the FDA official who approved the withdrawal order.

J. Proposed § 507.77—Timeframe for Issuing a Decision on an Appeal

Proposed § 507.77(a) would require that, if the owner, operator, or agent in charge of a facility appeals the order without requesting a hearing, the presiding officer must issue a written report that includes a final decision confirming or revoking the withdrawal by the tenth calendar day after the appeal is filed. Under proposed § 507.60, FDA would issue a withdrawal order either in the event of an active investigation of a foodborne illness outbreak that is directly linked to a qualified facility or if FDA determines that an exemption withdrawal is necessary to protect animal or human health and prevent or mitigate a foodborne illness outbreak based on conduct or conditions associated with a qualified facility that are material to the safety of the animal food located at the facility. The Agency tentatively concludes that it will need 10 calendar days to review the written appeal and the materials submitted with the written appeal, and that a final decision confirming or revoking a withdrawal order should be issued as quickly as possible in the interest of the public health and to provide reasonable due process that would come to closure sufficiently in advance of the effective date of the order to provide an opportunity for the facility to come into compliance if the Agency denies the appeal.

Proposed § 507.77(b)(1) would require that, if the owner, operator, or agent in charge of a facility appeals the order and requests an informal hearing and, if FDA grants the request for a hearing and the hearing is held, the presiding officer must provide a 2 calendar day opportunity for the hearing participants to review and submit comments on the report of the hearing under § 507.73(c)(4), and must issue a final decision within the 10 calendar day period after the hearing is held. The Agency tentatively concludes that it is appropriate to grant the owner, operator, or agent in charge of a qualified facility subject to a withdrawal order the opportunity to review and submit comments to the presiding officer's report because the report is part of the record of a final agency action (see discussion of proposed § 507.83 in this section of the document) that is not subject to further reconsideration by FDA. The presiding officer would have discretion to determine whether to revise the report of the hearing in light of any comments that might be submitted by any of the hearing participants.

Proposed § 507.77(b)(2) would require that, if the owner, operator, or agent in charge of a facility appeals the order and requests an informal hearing and if FDA denies the request for a hearing, the presiding officer must issue a final decision on the appeal confirming or revoking the withdrawal within 10 calendar days after the date the appeal is filed. The Agency tentatively concludes that ten calendar days for the presiding officer to issue a final decision is appropriate for purposes of the efficient adjudication of the appeal of a withdrawal order, would provide reasonable due process that would come to closure sufficiently in advance of the effective date of the order to provide an opportunity for the facility to come into compliance if the Agency denies the appeal, and is in the interest of animal or human health.

K. Proposed § 507.80—Revocation of an Order To Withdraw an Exemption Applicable to a Qualified Facility

Proposed § 507.80(a) through (c) would establish that an order to withdraw an exemption applicable to a qualified facility under § 507.5(c) is revoked if:

- The owner, operator, or agent in charge of the facility appeals the order and requests an informal hearing, FDA grants the request for an informal hearing, and the presiding officer does not confirm the order within the 10 calendar days after the hearing, or issues a decision revoking the order within that time; or
- The owner, operator, or agent in charge of the facility appeals the order and requests an informal hearing, FDA denies the request for an informal hearing, and FDA does not confirm the order within the 10 calendar days after the appeal is filed, or issues a decision revoking the order within that time; or
- The owner, operator, or agent in charge of the facility appeals the order without requesting an informal hearing, and FDA does not confirm the order within the 10 calendar days after the appeal is filed, or issues a decision revoking the order within that time.

The Agency tentatively concludes that an order to withdraw an exemption may be revoked in one of two manners. First, the Agency is proposing that the FDA officer responsible for adjudicating the appeal and presiding over a hearing, if one is granted, may expressly issue a written decision revoking the order within the specified 10 calendar day timeframes. Second, the Agency is proposing that the failure of the FDA officer responsible for adjudicating an appeal to issue a final decision expressly confirming the order within the specified timeframes will also serve to revoke the order. The Agency tentatively concludes that fairness would warrant the revocation of a withdrawal order if FDA is unable to meet the proposed deadlines for expressly confirming an order.

L. Proposed § 507.84—Final Agency Action

Proposed § 507.84 would establish that confirmation of a withdrawal order by the presiding officer is considered a final agency action for purposes of section 702 of title 5 of the United States Code (5 U.S.C. 702). A confirmation of an order withdrawing an exemption therefore would be reviewable by the courts under section 702 of title 5 and in accordance with § 10.45.

M. Conforming Amendment to 21 CFR Part 16

The Agency proposes to amend § 16.1(b)(2) to include part 507, subpart D, relating to the withdrawal of an exemption applicable to a qualified facility, to the list of regulatory provisions under which regulatory hearings are available.

XII. Proposed Subpart F—Requirements Applying to Records That Must Be Established and Maintained

A. Relevant Statutory Provisions

FDA is proposing to create a new subpart F to establish requirements applying to records that must be established and maintained according to the requirements of this proposed rule. As discussed in section X.J, section 418 of the FD&C Act prescribes several requirements relevant to recordkeeping. The statutory provisions that are most relevant to proposed subpart F are:

- Section 418(a) of the FD&C Act, which requires, in relevant part, that the owner, operator, or agent in charge of a facility maintain records of monitoring the performance of preventive controls as a matter of routine practice;
- Section 418(b)(3) of the FD&C Act, which requires, in relevant part, that the owner, operator, or agent in charge of a facility develop a written analysis of the hazards;
- Section 418(g) of the FD&C Act, which requires, in relevant part, that the owner, operator, or agent in charge of a facility maintain certain records for not less than 2 years. The records identified in section 418(g) include records documenting the monitoring of the preventive controls implemented under section 418(c) of the FD&C Act, instances of nonconformance material to food safety, the results of testing and other appropriate means of verification under section 418(f)(4) of the FD&C Act, instances when corrective actions were implemented, and the efficacy of preventive controls and corrective actions;
- Section 418(h) of the FD&C Act, which requires, in relevant part, that the owner, operator, or agent in charge of a facility prepare a written plan that documents and describes the procedures used by the facility to comply with the requirements of this section and that such written plan, together with documentation described in section 418(g) of the FD&C Act, shall be made promptly available to a duly authorized representative of the Secretary upon oral or written request;
- Section 418(n)(1)(A) of the FD&C Act, which provides, in relevant part, that FDA shall issue regulations to establish science-based minimum standards for documenting hazards and documenting the implementation of the preventive controls under this section;
- Section 402(a)(4) of the FD&C Act, which provides that food is adulterated if it has been prepared, packed, or held under insanitary conditions whereby it may have become contaminated with filth, or whereby it may have been rendered injurious to health;
- Section 701(a) of the FD&C Act 21 U.S.C. 371(a), which provides FDA with authority to issue regulations for the efficient enforcement of the FD&C Act;
- Section 361(a) of the Public Health Service Act (42 U.S.C. 264(a)), which provides FDA with authority to make and enforce such regulations as in FDA's judgment are necessary to prevent the introduction, transmission, or spread of communicable diseases from foreign countries into the States or possessions, or from one State or possession into any other State or possession; and
- Section 418(l)(2)(B) of the FD&C Act, which requires a qualified facility to submit documentation to the Secretary related to its qualified status and also submit either documentation of the facility's implementation and monitoring of preventive controls or documentation of its compliance with other appropriate non-Federal food safety laws.

B. Proposed § 507.100—Records Subject to the Requirements of This Subpart F

Proposed § 507.100(a) would establish that, except as provided by proposed § 507.100(d) and (e), all records required by proposed part 507 would be subject to all requirements of proposed subpart F. FDA tentatively concludes that the requirements in proposed subpart F describing how records must be established and maintained, including the general requirements, record retention requirements, and requirements for official review and public disclosure, are applicable to all records that would be required under all subparts, because records that would be required under each of the subparts aid plants and facilities in compliance with the requirements of proposed part 507; and allow plants and facilities to show, and FDA to determine, compliance with the requirements of proposed part 507.

Proposed § 507.100(b) would establish that all records required by proposed part 507 are subject to the disclosure requirements under part 20 (21 CFR part 20). FDA's regulations in part 20, the Freedom of Information Act (5 U.S.C. 552), the Trade Secrets Act (18 U.S.C. 1905), and the FD&C Act, govern FDA's disclosures of information, including treatment of commercial confidential information and trade secret information. The Agency's general policies, procedures, and practices relating to the protection of confidential information received from third parties would apply to information received under this rule.

Proposed § 507.100(c) would require that all records required by part 507 be made promptly available to a duly authorized representative of the Secretary upon oral or written request. Proposed § 507.100(c) implements subsection 418(h) of the FD&C Act and is necessary in order for FDA to determine compliance with the requirements of part 507.

Proposed § 507.100(c) does not explicitly require a facility to send records to the Agency rather than making the records available for review at a facility's place of business. FDA requests comments on whether proposed § 507.100(c) should be modified to explicitly address this circumstance, and if so, whether FDA should require that the records be submitted electronically. Obtaining a facility's food safety plan without going to a facility could be useful to FDA in a number of different circumstances, such as to determine whether a recently identified hazard is being addressed by affected facilities.

Proposed § 507.100(d) would establish that the requirements of proposed § 507.100 apply only to the written food safety plan and is discussed in more detail in section XII.D.

Proposed § 507.100(e) would provide that the requirements of § 507.102(a)(2), (a)(4), and (a)(5) and (b) do not apply to the records required by proposed § 507.7(e) pertaining to qualified facilities. As discussed in section VIII.D, proposed § 507.7(e) would require that a qualified facility maintain records relied upon to support the self-certification that would be required by proposed § 507.7(a). Such documentation would be directed to the financial basis (and, when applicable, percentage of sales to qualified end users) as well as to food safety practices at the qualified facility, and could range from invoices to a food safety plan to an operating license issued by a state or local authority. Such records would not be expected to satisfy the provisions of proposed § 507.102(a)(2), (a)(4), and (a)(5) and (b) (which are discussed in the next section). To make clear that a qualified facility need not comply with provisions that do not apply to its records, the Agency is proposing to specify that those provisions do not apply to such records.

C. Proposed § 507.102—General Requirements Applying to Records

Proposed § 507.102 contains general requirements that would apply to records that would be required under proposed part 507, including the format for required records, the recording of actual values and observations obtained during monitoring, when records must be created, and information that must be included in each record.

1. Proposed § 507.102(a)

Proposed § 507.102(a)(1) would require that the records be kept as original records, true copies (such as photocopies, pictures, scanned copies, microfilm, microfiche, or other accurate reproductions of the original records), or electronic records. True copies of records should be of sufficient quality to detect whether the original record was changed or corrected in a manner that obscured the original entry (e.g., through the use of white-out). Proposed § 507.102(a)(1) would provide flexibility for mechanisms for keeping records while maintaining the integrity of the recordkeeping system. The proposed requirement allowing true copies provides options that may be compatible with the way records are currently being kept in plants and facilities.

Proposed § 507.102(a)(1) also would require that electronic records be kept in accordance with part 11 (21 CFR part 11). Part 11 provides criteria for acceptance by FDA, under certain circumstances, of electronic records, electronic signatures, and handwritten signatures executed to electronic records as equivalent to paper records and handwritten signatures executed on paper. The proposed requirement clarifies and acknowledges that records required by part 507 may be retained electronically, provided that they comply with part 11.

FDA tentatively concludes that it is appropriate to apply the requirements of part 11 to the records that would be required to be kept under proposed part 507. However, the Agency requests comment on whether there are any circumstances that would warrant not applying part 11 to records that would be kept under proposed part 507. For example, would a requirement that electronic records be kept according to part 11 mean that current electronic records and recordkeeping systems would have to be recreated and redesigned, which the Agency determined to be the case in the regulation "Establishment and Maintenance of Records Under the Public Health Security and Bioterrorism Preparedness and Response Act of 2002" (69 FR 71562, December 9, 2004 (the BT records regulation)). For the purposes of the records requirements in the BT records regulation, the Agency concluded that it was not necessary for new recordkeeping systems to be established as long as current practices would satisfy the requirements of the Act and, therefore, the Agency exempted the records from the requirements of part 11 (§ 1.329(b)). The Agency also exempted records related to certain cattle materials prohibited from use in human food and cosmetics from part 11 (21 CFR 189.5(c)(7) and 700.27(c)(7), respectively). The Agency also seeks comment on whether it should allow additional time for electronic records to be kept in accordance with part 11. Comments should provide the basis for any view that the requirements of part 11 are not warranted.

2. Proposed § 507.102(a)(2)

Proposed § 507.102(a)(2)would require that records contain the actual values and observations obtained during monitoring. It is neither possible to derive the full benefits of a preventive controls system, nor to verify the operation of the system, without recording actual values and observations to produce an accurate record. Notations that monitoring measurements, such as heat treatment temperatures, are "satisfactory" or "unsatisfactory," without recording the actual times and temperatures, are vague and subject to varying interpretations and, thus, will not ensure that controls are working properly. In addition, it is not possible to discern a trend toward loss of control without actual measurement values.

3. Proposed § 507.102(a)(3), (a)(4), and (a)(5)

Proposed § 507.102(a)(3), (a)(4), and (a)(5) would require that records be accurate, indelible, and legible (proposed § 507.102(a)(3)); be created concurrently with performance of the activity documented (proposed

§ 507.102(a)(4)); and be as detailed as necessary to provide a history of work performed (proposed § 507.102(a)(5)). Proposed § 507.102(a)(3) and (a)(4) would ensure that the records are useful to the owner, operator, or agent in charge of a plant or facility in complying with the requirements of proposed part 507, for example, in documenting compliance with monitoring requirements and verifying compliance with the food safety plan. These proposed requirements would also ensure that the records would be useful to FDA in determining compliance with the requirements of proposed part 507. Proposed § 507.102(a)(5) would provide flexibility to plants and facilities to tailor the amount of detail to the nature of the record.

4. Proposed § 507.102(b)

Proposed § 507.102(b)would require that the records include: (1) The name and location of the plant or facility; (2) the date and time of the activity documented; (3) the signature or initials of the person performing the activity; and (4) where appropriate, the identity of the product and the production code, if any. The name and location of the plant or facility and the date and time would allow the owner, operator, or agent in charge of a plant or facility (and, during inspection, an FDA investigator) to assess whether the record is current, to identify when and where any deviation occurred, and to track corrective actions. The signature of the individual who made the observation would ensure responsibility and accountability. In addition, if there is a question about the record, a signature would ensure that the source of the record will be known. Linking a record to a specific product (and, when applicable, the production code) would enable the owner, operator, or agent in charge of a facility to isolate product that has not been processed properly when there has been a problem, thereby limiting the impact of the problem (such as the need to reprocess product or to recall product) to only those lots with the problem.

D. Proposed § 507.106—Additional Requirements Applying to the Food Safety Plan

Proposed § 507.106 would require that the owner, operator, or agent in charge of a facility sign and date the food safety plan upon initial completion and upon any modification. Such a signature would provide direct evidence of the owner, operator, or agent's acceptance of the plan and commitment to implementation of the plan. Additionally, the signature, along with the date of signing, would serve to minimize potential confusion over the authenticity of any differing versions or editions of the document that might exist.

E. Proposed § 507.108—Requirements for Record Retention

Proposed § 507.108 contains requirements on the length of time records that would be required under proposed part 507 must be retained and allowances for offsite storage of records under certain circumstances.

1. Proposed § 507.108(a) and (b)

Proposed § 507.108(a) would require that all records that would be required by proposed part 507 be retained at the plant or facility for at least 2 years after the date they were prepared. Proposed § 507.108(b) would require that records that relate to the general adequacy of the equipment or processes being used by a facility, including the results of scientific studies and evaluations, must be retained at the facility for at least 2 years after their use is discontinued (e.g., because the facility has updated the written food safety plan (§ 507.30) or records that document validation of the written food safety plan (§ 507.45(a)). Proposed § 507.108(a) and (b) implement subsection 418(g) of the FD&C Act, which requires certain records to be maintained for not less than 2 years.

While FDA established shorter records retention requirements for records related to perishable foods in the BT records, seafood HACCP, and juice HACCP regulations, in this case Congress determined and specified in section 418(g) of the FD&C Act that the minimum retention period for the majority of the records required under the implementing regulations for all foods, regardless of perishability, be 2 years. Therefore, FDA tentatively concludes that the same requirement should apply to all records required under this section, regardless of the perishability of the food to which the record relates. This would simplify plants' or facilities' duties in compliance because there would only be one 2-year retention period to apply to any record required under proposed part 507. This 2-year retention period would run either from the date the record was prepared, for day-to-day operational records; or from the date at which use of the record is discontinued, for records relating to the general adequacy or equipment or processes (e.g., the written food safety plan and records that document validation of the written food safety plan). The Agency requests comments on the record keeping requirements for animal food, including whether the Agency should use its authority in section 418(m) of the FD&C Act to modify these requirements with respect to facilities that are solely engaged in the production of food for animals other than man.

2. Proposed § 507.108(c)

Proposed § 507.108(c) would provide that, except for the food safety plan, use of offsite storage for records is permitted after 6 months following the date that the record was made if such records can be retrieved and provided onsite within 24 hours of request for official review. The food safety plan would be required to remain onsite. FDA realizes that the proposed requirements for recordkeeping could require some plants or facilities to store a significant quantity of records, and that there may not be adequate storage space in the plant or facility for all of these records. Providing for offsite storage of most records after 6 months would enable a facility to comply with the proposed requirements for record retention while reducing the amount of space needed for onsite storage of the records without interfering with the purpose of record retention, because the records will be readily available.

Proposed § 507.108(c) would also provide that electronic records are considered to be onsite if they are accessible from an onsite location. Computerized systems within corporations can be networked, allowing for the sending and receiving of information in a secure fashion to all of the different food processing facilities of that corporation worldwide. This type of system can be used to provide access at multiple locations to records from multiple plants or facilities.

3. Proposed § 507.108(d)

Proposed § 507.108(d) would provide that if the plant or facility is closed for a prolonged period, the records may be transferred to some other reasonably accessible location but must be returned to the plant or facility within 24 hours for official review upon request. Allowing for transfer of records will give practical storage relief to seasonal operations or those closed for other reasons for prolonged periods.

XIII. FSMA's Rulemaking Provisions

Please see this discussion in section XVI of the document for the proposed rule for preventive controls for human food (78 FR 3646).

XIV. Proposed Conforming Changes

FDA is proposing conforming changes to several applicable sections of the CFR that would add a reference to part 507. The affected sections in title 21 CFR are:

- § 225.1 Current good manufacturing practice;
- § 500.23 Thermally processed low-acid foods packaged in hermetically sealed containers; and
- § 579.12 Incorporation of regulations in part 179.

XV. Legal Authority

FDA is proposing the CGMP regulations under the FD&C Act and the Public Health Service Act. FDA is proposing all other requirements under the FDA Food Safety Modernization Act, the FD&C Act, the Public Health Service Act, and the FDAAA of 2007.

A. Current Good Manufacturing Practice Regulations

FDA is proposing CGMP requirements in proposed subparts A, B, and F. FDA's legal authority to require CGMPs derives from sections 402(a)(3), 402(a)(4) and 701(a) of the FD&C Act (21 U.S.C. 342(a)(3), 342(a)(4), and 371(a)). Section 402(a)(3) of the FD&C Act provides that a food is adulterated if it consists in whole or in part of any filthy, putrid, or decomposed substance, or if it is otherwise unfit for food. Section 402(a)(4) of the FD&C Act provides that a food is adulterated if it has been prepared, packed, or held under insanitary conditions whereby it may have become contaminated with filth, or whereby it may have been rendered injurious to health. Under section 701(a) of the FD&C Act, FDA is authorized to issue regulations for the efficient enforcement of the FD&C Act. The proposed rule also includes new requirements necessary to prevent food from being adulterated (either because it consists in whole or in part of a filthy, putrid, or decomposed substance, because it is otherwise unfit for food, or because it has been held under insanitary conditions whereby it may have become contaminated with filth, or whereby it may have been rendered injurious to health). A regulation that requires measures to prevent food from being held under insanitary conditions whereby either of the proscribed results may occur allows for the efficient enforcement of the FD&C Act. See, e.g., regulations to require HACCP systems for fish and fishery products (part 123) and juice (part 120), regulations to require a safe handling statement on cartons of shell eggs that have not been treated to destroy *Salmonella* organisms and to require refrigeration of shell eggs held for retail distribution (part 101 and 21 CFR part 115), and regulations for the production, storage, and transportation of shell eggs (21 CFR part 118).

In addition to the FD&C Act, FDA's legal authority for the proposed CGMP requirements derives from the PHS Act to the extent such measures are related to communicable disease. Authority under the PHS Act for the proposed regulations is derived from the provisions of sections 311, 361, and 368 (42 U.S.C. 243, 264, and 271) that relate to communicable disease. The PHS Act authorizes the Secretary to make and enforce such regulations as "are necessary to prevent the introduction, transmission, or spread of communicable diseases from foreign countries into the States . . . or from one State . . . into any other State" (section 361(a) of the PHS Act). (See sec. 1, Reorg. Plan No. 3 of 1966 at 42 U.S.C. 202 for transfer of authority from the Surgeon General to the Secretary.) Many provisions in the proposed rule are necessary to prevent animal food from being contaminated with microorganisms of human health significance, such as *Salmonella,* and therefore to prevent the introduction, transmission, or spread of communicable disease from foreign countries into the United States, or from one state in the United States to another. As discussed in section II.E and X.C.6, lack of adequate sanitation in food establishments can lead to the contamination of food with pathogens, increasing the likelihood of illness in humans consuming products derived from animals (such as milk and eggs) and illness in humans handling animal food, particularly in the household setting. The Agency tentatively concludes that the proposed CGMPs are necessary to prevent the spread of communicable disease and to prevent animal food from containing filthy, putrid, or decomposed substances, being otherwise unfit for food, or being prepared, packed, or held under insanitary conditions whereby it may have become contaminated with filth, or whereby it may have been rendered injurious to health.

B. Hazard Analysis and Risk-Based Preventive Controls

Section 103 of FSMA, Hazard Analysis and Risk-Based Preventive Controls, amends the FD&C Act to create a new section 418, which mandates rulemaking. Section 418(n)(1)(A) of the FD&C Act requires that the Secretary issue regulations to establish science-based minimum standards for conducting a hazard analysis, documenting hazards, implementing preventive controls, and documenting the implementation of the preventive controls. Section 418(n)(1)(B) of the FD&C Act requires that the regulations define the terms "small business" and "very small business," taking into consideration the study of the food processing sector required by section 418(l)(5) of the FD&C Act. Section 103(e) of FSMA creates a new section 301(uu) in the FD&C Act (21 U.S.C. 331(uu)) to prohibit the operation of a facility that manufactures, processes, packs, or holds food for sale in the United States if the owner, operator, or agent in charge of such facility is not in compliance with section 418 of the FD&C Act.

In addition to rulemaking requirements, section 418 contains requirements applicable to the owner, operator, or agent in charge of a facility required to register under section 415. Section 418(a) is a general provision that requires the owner, operator, or agent in charge of a facility to evaluate the hazards that could affect food manufactured, processed, packed, or held by the facility, identify and implement preventive controls, monitor the performance of those controls, and maintain records of the monitoring. Section 418(a) specifies that the purpose of the preventive controls is, in relevant part, to prevent the occurrence of such hazards and provide assurances that such food is not adulterated under section 402 of the FD&C Act. In addition to the general requirements in section 418(a) of the FD&C Act, sections 418(b)–(i) contain more specific requirements applicable to facilities. These include hazard analysis (§ 418(b)), preventive controls (§ 418(c)), monitoring (§ 418(d)), corrective actions (§ 418(e)), verification (§ 418(f)), recordkeeping (§ 418(g)), a written plan and documentation (§ 418(h)), and reanalysis of hazards (§ 418(i)). Proposed requirements (proposed subparts C and F) that would implement these provisions of section 418 of the FD&C Act are discussed in sections X and XII.

The Agency is proposing certain requirements in order to efficiently enforce these requirements of section 418. For example, section 418(g) and (h) of the FD&C Act prescribe certain recordkeeping, maintenance, and access requirements for certain kinds of records. As discussed in section XII, the Agency is proposing to establish one set of requirements that would apply to all records that would be required under the proposed rule. This approach will facilitate compliance with the rule on the part of facilities, and will allow for efficient enforcement of the requirements of the FD&C Act.

Section 418(j) through (m) of the FD&C Act and section 103(c)(1)(D) and (g) of FSMA provide authority for certain exemptions and modifications to the requirements of section 418 of the FD&C Act. These include provisions related to low-acid canned food (section 418(j)); activities of facilities subject to section 419 of the FD&C Act (Standards for Produce Safety) (section 418(k)); qualified facilities (section 418(l)); facilities that are solely engaged in the production of food for animals other than man, the storage of raw agricultural commodities (other than fruits and vegetables) intended for further distribution or processing, or the storage of packaged foods that are not exposed to the environment (section 418(m)); and facilities engaged only in certain low-risk on-farm activities on certain foods conducted by small or very small businesses (section 103(c)(1)(D) of FSMA). Proposed provisions that would implement these provisions of section 418 of the FD&C Act and section 103 of FSMA are discussed in sections VII, VIII, and X.

FDA tentatively concludes that the provisions in proposed subpart C and related requirements in proposed subparts A, D, and F should be applicable to activities that are intrastate in character. Facilities are required to register under section 415 of the FD&C Act regardless of whether the food from the facility enters interstate commerce (§ 1.225(b)). The plain language of section 418 of the FD&C Act applies to facilities that are required to register under section 415 (section 418(o)(2) of the FD&C Act) and does not exclude a facility because food from such a facility is not in interstate commerce. Section 301(uu) of the FD&C Act provides that "the operation of a facility that manufactures, processes, packs, or holds food for sale in the United States if the owner, operator, or agent in charge of such facility is not in compliance with section 418", or the causing thereof, is a prohibited act.

FDA also is proposing the provisions in subpart C and related requirements in subparts A, D, and F, under sections 402(a)(3), (a)(4), and 701(a) of the FD&C Act to the extent such requirements are necessary to prevent food from being held under insanitary conditions whereby it may become contaminated with filth or rendered injurious to health, or being unfit for food. FDA is also proposing those provisions under sections 311, 361, and 368 of the PHS Act relating to communicable disease to the extent those provisions are necessary to prevent the interstate spread of communicable disease.

The animal food safety system that the Agency is proposing would require a facility to conduct a hazard analysis to determine those hazards that are reasonably likely to occur and establish and implement preventive controls for those hazards. To ensure that controls are properly implemented and effectively controlling the hazards, the proposed animal food safety system would establish requirements for monitoring, corrective actions, and verification, including validation that the preventive controls are adequate to control the identified hazards. The proposed animal food safety system also would require a recall plan. Certain activities would be required to be conducted (or overseen) by a qualified individual and certain activities would be required to be documented. A written food safety plan would include the hazard analysis, the preventive controls that would be established and implemented to address those hazards determined to be reasonably likely to occur, procedures for monitoring, corrective actions, and verification; and a recall plan. The written plan and other documentation would be required to be made promptly available to a duly authorized representative of the Secretary upon oral or written request. FDA tentatively concludes that, taken as a whole, the animal food safety system described here is necessary to help prevent food safety problems associated with biological, chemical, physical, and radiological hazards in animal foods. Therefore, the proposed system is necessary to prevent animal food from being adulterated because it is unfit for food or because it has been held under insanitary conditions whereby it may become contaminated with filth or may be rendered injurious to health and to prevent the spread of communicable disease.

Finally, FDA is proposing the provisions in subparts B and C and related requirements in subparts A, D, and F, under section 1002(a) of Title X of the FDAAA of 2007 (21 U.S.C. 2102), which requires the Secretary to establish processing standards for pet food. The proposed animal food safety system would require tailored standards for facilities processing animal food (including animal feed, pet food, and their raw materials and ingredients).

XVI. Preliminary Regulatory Impact Analysis

A. Overview

FDA has examined the impacts of this proposed rule under Executive Order 12866, Executive Order 13563, the Regulatory Flexibility Act (5 U.S.C. 601–612), and the Unfunded Mandates Reform Act of 1995 (Pub. L. 104–4). Executive Orders 12866 and 13563 direct Agencies to assess all costs and benefits of available regulatory alternatives and, when regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety, and other advantages; distributive impacts; and equity). FDA has developed a PRIA that presents the benefits and costs of this proposed rule (Ref. 52). FDA believes that the proposed rule will be a significant regulatory action as defined by Executive Order 12866. FDA requests comments on the PRIA.

The summary analysis of benefits and costs included in this document is drawn from the detailed PRIA (Ref. 52) which is available at *http://www.regulations.gov* (enter Docket No. FDA–2011–N–0922), and is also available on FDA's Web site at *http://www.fda.gov/downloads/Food/GuidanceRegulation/FSMA/UCM366905.pdf.*

B. Regulatory Flexibility Act

The Regulatory Flexibility Act requires Agencies to analyze regulatory options that would minimize any significant impact of a rule on small entities. Because many small businesses will need to implement a number of new preventive controls, FDA acknowledges that the final rules resulting from this proposed rule will have a significant economic impact on a substantial number of small entities.

C. Small Business Regulatory Enforcement Fairness Act of 1996

The Small Business Regulatory Enforcement Fairness Act of 1996 (Pub. L. 104–121) defines a major rule for the purpose of congressional review as having caused or being likely to cause one or more of the following: An annual effect on the economy of $100 million or more; a major increase in costs or prices; significant adverse effects on competition, employment, productivity, or innovation; or significant adverse effects on the ability of United States-based enterprises to compete with foreign-based enterprises in domestic or export markets. In accordance with the Small Business Regulatory Enforcement Fairness Act, the Office of Management and Budget (OMB) has determined that this proposed rule is a major rule for the purpose of congressional review.

D. Unfunded Mandates Reform Act of 1995

Section 202(a) of the Unfunded Mandates Reform Act of 1995 requires that Agencies prepare a written statement, which includes an assessment of anticipated costs and benefits, before proposing "any rule that includes any Federal mandate that may result in the expenditure by State, local, and tribal governments, in the aggregate, or by the private sector, of $100,000,000 or more (adjusted annually for inflation) in any one year." The current threshold after adjustment for inflation is $141 million, using the most current (2012) Implicit Price Deflator for the Gross Domestic Product. FDA expects that the proposed rule will result in a 1-year expenditure that would exceed this amount.

E. Public Access to the Analyses

The analyses that FDA has performed in order to examine the impacts of this proposed rule under Executive Order 12866, Executive Order 13563, the Regulatory Flexibility Act (5 U.S.C. 601–612), and the Unfunded Mandates Reform Act of 1995 (Pub. L. 104–4) are available to the public in the docket for this proposed rule (Ref. 52).

XVII. Paperwork Reduction Act of 1995

This proposed rule contains information collection provisions that are subject to review by OMB under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520). The collections of information in the proposed rule have been submitted to OMB for review under section 3507(d) of the Paperwork Reduction Act of 1995. FDA invites comments on: (1) Whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical utility; (2) the accuracy of FDA's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

To ensure that comments on information collection are received, OMB recommends that written comments be faxed to the Office of Information and Regulatory Affairs, OMB, Attn: FDA Desk Officer, FAX: 202–395–7285, or emailed to *oira_submission@omb.eop.gov.* All comments should be identified with the title "Current Good Manufacturing Practice And Hazard Analysis And Risk-Based Preventive Controls For Food For Animals."

In compliance with the Paperwork Reduction Act of 1995 (44 U.S.C. 3407(d)), the Agency has submitted the information collection provisions of this proposed rule to OMB for review. These requirements will not be effective until FDA obtains OMB approval. FDA will publish a notice concerning OMB approval of these requirements in the **Federal Register**.

The analyses that FDA has performed in order to examine the impacts of this proposed rule under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520) is available to the public in the docket (Docket No. FDA–2011–N–0922) for this proposed rule (Ref. 96).

XVIII. Analysis of Environmental Impact

FDA has determined under 21 CFR 25.30(j) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

XIX. Federalism

FDA has analyzed this proposed rule in accordance with the principles set forth in Executive Order 13132. FDA has determined that the proposed rule, if finalized, would not contain policies that would have substantial direct effects on the States, on the relationship between the National Government and the States, or on the distribution of power and responsibilities among the various levels of government. Accordingly, the Agency tentatively concludes that the proposed rule does not contain policies that have federalism implications as defined in the Executive order and, consequently, a federalism summary impact statement is not required.

XX. Comments

Interested persons may submit either electronic comments regarding this document to *http://www.regulations.gov* or written comments to the Division of Dockets Management (see **ADDRESSES**). It is only necessary to send one set of comments. Identify comments with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday, and will be posted to the docket at *http://www.regulations.gov.*

XXI. References

The following references have been placed on display in the Division of Dockets Management (see **ADDRESSES**) and may be seen by interested persons between 9 a.m. and 4 p.m., Monday through Friday, and are available electronically at *http://www.regulations.gov.* (FDA has verified the Web site addresses, but FDA is not responsible for any subsequent changes to the Web sites after this document publishes in the **Federal Register**.)

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2. Food and Agriculture Organization of the United Nations (FAO) and International Feed Industry Federation (IFIF), "Good practices for the feed industry—Implementing the Codex Alimentarius Code of Practice on Good Animal Feeding" 2010.

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List of Subjects

21 CFR Part 16

Administrative practice and procedure.

21 CFR Part 225

Animal drugs, Animal feeds, Labeling, Packaging and containers, Reporting and recordkeeping requirements.

21 CFR Part 500

Animal drugs, Animal feeds, Cancer, Labeling, Packaging and containers, Polychlorinated biphenyls (PCB’s).

21 CFR Part 507

Animal foods, Labeling, Packaging and containers, Reporting and recordkeeping requirements.

21 CFR Part 579

Animal feeds, Animal foods, Radiation protection.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, it is proposed that 21 CFR chapter I be amended as follows:

PART 16—REGULATORY HEARING BEFORE THE FOOD AND DRUG ADMINISTRATION

■ 1. The authority citation for 21 CFR part 16 continues to read as follows:

Authority: 15 U.S.C. 1451–1461; 21 U.S.C. 141–149, 321–394, 467f, 679, 821, 1034; 28 U.S.C. 2112; 42 U.S.C. 201–262, 263b, 364.

■ 2. In § 16.1, in paragraph (b)(2) add the following entry in numerical order to read as follows:

§ 16.1 Scope.

* * * * *

(b) * * *

(2) * * *

§§ 507.60 through 507.83 (part 507, subpart D) relating to withdrawal of exemption applicable to a qualified facility.

* * * * *

PART 225—CURRENT GOOD MANUFACTURING PRACTICE FOR MEDICATED FEEDS

■ 3. The authority citation for 21 CFR part 225 continues to read as follows:

Authority: 21 U.S.C. 351, 352, 360b, 371, 374.

■ 4. In § 225.1, add paragraph (d) to read as follows:

§ 225.1 Current good manufacturing practice.

* * * * *

(d) In addition, non-medicated feed is subject to part 507 of this chapter.

PART 500—GENERAL

■ 5. The authority citation for 21 CFR part 500 continues to read as follows:

Authority: 21 U.S.C. 321, 331, 342, 343, 348, 351, 352, 353, 360b, 371, 379e.

■ 6. Revise § 500.23 to read as follows:

§ 500.23 Thermally processed low-acid foods packaged in hermetically sealed containers.

Except as provided in § 507.5(b), the provisions of parts 507 and 113 of this chapter apply to the manufacturing, processing, or packing of low-acid foods in hermetically sealed containers, and intended for use as food for animals.

■ 7. Add part 507 to read as follows:

PART 507—CURRENT GOOD MANUFACTURING PRACTICE AND HAZARD ANALYSIS AND RISK–BASED PREVENTIVE CONTROLS FOR FOOD FOR ANIMALS

Subpart A—General Provisions

Sec.
507.1 Applicability and status.
507.3 Definitions.
507.5 Exemptions.
507.7 Requirements that apply to a qualified facility.
507.10 Applicability of subpart C to a facility solely engaged in the storage of packaged animal food that is not exposed to the environment.

Subpart B—Current Good Manufacturing Practice

507.14 Personnel.
507.17 Plant and grounds.
507.19 Sanitary operations.
507.20 Sanitary facilities and controls.
507.22 Equipment and utensils.
507.25 Processes and controls.
507.28 Warehousing and distribution.

Subpart C—Hazard Analysis and Risk-Based Preventive Controls

507.30 Requirement for a food safety plan.
507.33 Hazard analysis.
507.36 Preventive controls for hazards that are reasonably likely to occur.
507.38 Recall plan for animal food with a hazard that is reasonably likely to occur.
507.39 Monitoring.
507.42 Corrective actions.
507.45 Verification.
507.48 Modified requirements that apply to a facility solely engaged in the storage of packaged animal food that is not exposed to the environment.
507.50 Requirements applicable to a qualified individual.
507.55 Records required for this subpart C.

Subpart D—Withdrawal of an Exemption Applicable to a Qualified Facility

507.60 Circumstances that may lead FDA to withdraw an exemption applicable to a qualified facility.
507.62 Issuance of an order to withdraw an exemption applicable to a qualified facility.
507.65 Contents of an order to withdraw an exemption applicable to a qualified facility.
507.67 Compliance with, or appeal of, an order to withdraw an exemption applicable to a qualified facility.
507.69 Procedure for submitting an appeal.
507.71 Procedure for requesting an informal hearing.
507.73 Requirements applicable to an informal hearing.
507.75 Presiding officer for an appeal and for an informal hearing.
507.77 Timeframe for issuing a decision on an appeal.
507.80 Revocation of an order to withdraw an exemption applicable to a qualified facility.
507.83 Final agency action.

Subpart E—[Reserved]

Subpart F—Requirements Applying to Records That Must Be Established and Maintained

507.100 Records subject to the requirements of this subpart F.
507.102 General requirements applying to records.
507.106 Additional requirements applying to the food safety plan.
507.108 Requirements for record retention.

Authority: 21 U.S.C. 321, 331, 342, 350c, 350d note, 350g, 350g note, 371, 374; 42 U.S.C. 243, 264, 271.

Subpart A—General Provisions

§ 507.1 Applicability and status.

(a) The criteria and definitions in this part will apply in determining whether an animal food is adulterated:

(1) Within the meaning of section 402(a)(3) of the Federal Food, Drug, and

Cosmetic Act in that the food has been manufactured under such conditions that it is unfit for food; or

(2) Within the meaning of section 402(a)(4) of the Federal Food, Drug, and Cosmetic Act in that the food has been prepared, packed, or held under insanitary conditions whereby it may have become contaminated with filth, or whereby it may have been rendered injurious to health. The criteria and definitions in this part also apply in determining whether an animal food is in violation of section 361 of the Public Health Service Act (42 U.S.C. 264).

(b) The operation of a facility that manufactures, processes, packs, or holds animal food for sale in the United States if the owner, operator, or agent in charge of such facility is required to comply with and is not in compliance with section 418 of the Federal Food, Drug, and Cosmetic Act or subparts C, D, and F of this part and § 507.7 is a prohibited act under section 301(uu) of the Federal Food, Drug, and Cosmetic Act.

(c) Animal food covered by specific current good manufacturing practice regulations also is subject to the requirements of those regulations.

(d) Animal food for sale in the United States must be manufactured, processed, packed, and held in accordance with the requirements in this part, subject to the exemptions in § 507.5. If a facility is required to comply with subpart B of this part and is also required to comply with subpart B of part 117 of this chapter because the facility manufactures, processes, packs, or holds human food, then the facility may choose to comply with the requirements in subpart B of part 117, instead of subpart B of part 507, as to the manufacturing, processing, packing, and holding of animal food at that facility. If a facility is required to comply with subpart C of part 507 and is also required to comply with subpart C of part 117 of this chapter, then the facility may choose to comply with the requirements in subpart C of part 117 as to the manufacturing, processing, packing, and holding of animal food at the facility, instead of subpart C of part 507, so long as the food safety plan also addresses all hazards that are reasonably likely to occur in the animal food, including nutrient imbalances. In both instances, when applying the requirements of part 117 of this chapter to animal food, the term "food" in part 117 includes animal food.

§ 507.3 Definitions.

The definitions and interpretations contained in section 201 of the Federal Food, Drug, and Cosmetic Act apply to such terms when used in this part. The following definitions also apply:

Adequate means that which is needed to accomplish the intended purpose in keeping with good public health practice.

Affiliate means any facility that controls, is controlled by, or is under common control with another facility.

Animal food means food for animals other than man and includes pet food, animal feed, and raw materials and ingredients.

Batter means a semifluid substance, usually composed of flour and other ingredients, into which principal components of food are dipped or with which they are coated, or which may be used directly to form bakery foods.

Blanching, except for tree nuts and peanuts, means a prepackaging heat treatment of foodstuffs for a sufficient time and at a sufficient temperature to partially or completely inactivate the naturally occurring enzymes and to effect other physical or biochemical changes in the food.

Calendar day means every day shown on the calendar.

Critical control point means a point, step, or procedure in a food process at which control can be applied and is essential to prevent or eliminate a food safety hazard or reduce such hazard to an acceptable level.

Environmental pathogen means a microorganism that is of animal or human health significance and is capable of surviving and persisting within the manufacturing, processing, packing, or holding environment.

Facility means a domestic facility or a foreign facility that is required to register under section 415 of the Federal Food, Drug, and Cosmetic Act, in accordance with the requirements of 21 CFR part 1, subpart H.

Farm means farm as defined in § 1.227(b) of this chapter.

FDA means the Food and Drug Administration.

Food means food as defined in section 201(f) of the Federal Food, Drug, and Cosmetic Act and includes raw materials and ingredients.

Food-contact surfaces are those surfaces that contact animal food and those surfaces from which drainage, or other transfer, onto the food or onto surfaces that contact the food ordinarily occurs during the normal course of operations. "Food-contact surfaces" include food-contact surfaces of utensils and equipment.

Harvesting applies to farms and farm mixed-type facilities and means activities that are traditionally performed by farms for the purpose of removing raw agricultural commodities from the place they were grown or raised and preparing them for use as food. Harvesting is limited to activities performed on raw agricultural commodities on the farm on which they were grown or raised, or another farm under the same ownership. Harvesting does not include activities that transform a raw agricultural commodity, as defined in section 201(r) of the Federal Food, Drug, and Cosmetic Act, into a processed food as defined in section 201(gg). Gathering, washing, trimming of outer leaves of, removing stems and husks from, sifting, filtering, threshing, shelling, and cooling raw agricultural commodities grown on a farm or another farm under the same ownership are examples of harvesting.

Hazard means any biological, chemical, physical, or radiological agent that is reasonably likely to cause illness or injury in animals or humans in the absence of its control.

Hazard reasonably likely to occur means a hazard for which a prudent person who manufactures, processes, packs, or holds food would establish controls because experience, illness data, scientific reports, or other information provides a basis to conclude that there is a reasonable possibility that the hazard will occur in the type of food being manufactured, processed, packed, or held in the absence of those controls.

Holding means storage of food. Holding facilities include warehouses, cold storage facilities, storage silos, grain elevators, and liquid storage tanks. For farms and farm mixed-type facilities, holding also includes activities traditionally performed by farms for the safe or effective storage of raw agricultural commodities grown or raised on the same farm or another farm under the same ownership, but does not include activities that transform a raw agricultural commodity, as defined in section 201(r) of the Federal Food, Drug, and Cosmetic Act, into a processed food as defined in section 201(gg).

Lot means the food produced during a period of time indicated by a specific code.

Manufacturing/processing means making food from one or more ingredients, or synthesizing, preparing, treating, modifying, or manipulating food, including food crops or ingredients. Examples of manufacturing/processing activities are cutting, peeling, trimming, washing, waxing, eviscerating, rendering, cooking, baking, freezing, cooling, pasteurizing, homogenizing, mixing, formulating, bottling, milling, grinding, extracting juice, distilling, labeling, or packaging. For farms and farm mixed-type facilities, manufacturing/processing does not include activities that are part of harvesting, packing, or holding.

Microorganisms means yeasts, molds, bacteria, viruses, protozoa, and microscopic parasites and includes species having animal or human health significance. The term "undesirable microorganisms" includes those microorganisms that are of animal or human health significance, that subject food to decomposition, that indicate that food is contaminated with filth, or that otherwise may cause food to be adulterated.

Mixed-type facility means an establishment that engages in both activities that are exempt from registration under section 415 of the Federal Food, Drug, and Cosmetic Act and activities that require the establishment to be registered. An example of such a facility is a "farm mixed-type facility," which is an establishment that grows and harvests crops or raises animals and may conduct other activities within the farm definition, but also conducts activities that require the establishment to be registered.

Monitor means to conduct a planned sequence of observations or measurements to assess whether a process, point, or procedure is under control and to produce an accurate record for use in verification.

Packaging (when used as a verb) means placing food into a container that directly contacts the food and that the consumer receives.

Packing means placing food into a container other than packaging the food. For farms and farm mixed-type facilities, packing also includes activities traditionally performed by farms to prepare raw agricultural commodities grown or raised on the same farm or another farm under the same ownership for storage and transport, but does not include activities that transform a raw agricultural commodity, as defined in section 201(r) of the Federal Food, Drug, and Cosmetic Act, into a processed food as defined in section 201(gg).

Pest refers to any objectionable animals or insects including birds, rodents, flies, and larvae.

Plant means the building or establishment, or parts thereof, used for or in connection with the manufacturing, processing, packing, or holding of animal food.

Preventive controls means those risk-based, reasonably appropriate procedures, practices, and processes that a person knowledgeable about the safe manufacturing, processing, packing, or holding of food would employ to significantly minimize or prevent the hazards identified under the hazard analysis that are consistent with the current scientific understanding of safe food manufacturing, processing, packing, or holding at the time of the analysis.

Qualified end-user, with respect to an animal food, means the consumer of the food (where the term does not include a business); or a restaurant or retail food establishment (as those terms are defined in § 1.227(b) of this chapter) that:

(1) Is located:

(i) In the same State as the qualified facility that sold the food to such restaurant or retail food establishment; or

(ii) Not more than 275 miles from such facility; and

(2) Is purchasing the food for sale directly to consumers at such restaurant or retail food establishment.

Qualified facility means (when including the sales by any subsidiary; affiliate; or subsidiaries or affiliates, collectively, of any entity of which the facility is a subsidiary or affiliate) a facility that is a very small business as defined in this part, or a facility to which both of the following apply:

(1) During the 3-year period preceding the applicable calendar year, the average annual monetary value of the animal food manufactured, processed, packed, or held at such facility that is sold directly to qualified end-users (as defined in this part) during such period exceeded the average annual monetary value of the animal food sold by such facility to all other purchasers; and

(2) The average annual monetary value of all animal food sold during the 3-year period preceding the applicable calendar year was less than $500,000, adjusted for inflation.

Qualified individual means a person who has successfully completed training in the development and application of risk-based preventive controls at least equivalent to that received under a standardized curriculum recognized as adequate by FDA, or is otherwise qualified through job experience to develop and apply a food safety system.

Quality control operation means a planned and systematic procedure for taking all actions necessary to prevent food from being adulterated.

Reasonably foreseeable hazard means a potential biological, chemical, physical, or radiological hazard that may be associated with the facility, or the food.

Rework means clean, unadulterated food that has been removed from processing for reasons other than insanitary conditions or that has been successfully reconditioned by reprocessing and that is suitable for use as food.

Safe moisture level is a level of moisture low enough to prevent the growth of undesirable microorganisms in the finished product under the intended conditions of manufacturing, processing, packing, and holding. The safe moisture level for a food is related to its water activity (a_w). An a_w will be considered safe for a food if adequate data are available that demonstrate that the food at or below the given a_w will not support the growth of undesirable microorganisms.

Sanitize means to adequately treat cleaned food-contact surfaces by a process that is effective in destroying vegetative cells of microorganisms of animal or human health significance, and in substantially reducing numbers of other undesirable microorganisms, but without adversely affecting the product or its safety for animals or humans.

Should is used to state recommended or advisory procedures or identify recommended equipment. Should denotes non-binding guidance.

Significantly minimize means to reduce to an acceptable level, including to eliminate.

Small business means, for purposes of this part, a business employing fewer than 500 persons.

Subsidiary means any company that is owned or controlled directly or indirectly by another company.

Validation means that element of verification focused on collecting and evaluating scientific and technical information to determine whether the food safety plan, when properly implemented, will effectively control the identified hazards.

Verification means those activities, other than monitoring, that establish the validity of the food safety plan and that the system is operating according to the plan.

Option 1 for Definition of "Very Small Business"

Very small business means, for purposes of this part, a business that has less than $500,000 in total annual sales of animal food, adjusted for inflation.

Option 2 for Definition of "Very Small Business"

Very small business means, for purposes of this part, a business that has less than $1,000,000 in total annual sales of animal food, adjusted for inflation.

Option 3 for Definition of "Very Small Business"

Very small business means, for purposes of this part, a business that has less than $2,500,000 in total annual sales of animal food, adjusted for inflation.

Water activity (a_w) means a measure of the free moisture in a food and is the quotient of the water vapor pressure of the substance divided by the vapor pressure of pure water at the same temperature.

§ 507.5 Exemptions.

(a) This part does not apply to establishments (including "farms" as defined in § 1.227(b) of this chapter) that are not required to register under section 415 of the Federal Food, Drug, and Cosmetic Act.

(b) Activities in animal food facilities that are regulated under, and are in compliance with, § 500.23 and part 113 of this chapter (Thermally Processed Low-Acid Foods Packaged in Hermetically Sealed Containers) are exempt from subpart C of part 507 only with respect to those microbiological hazards regulated under part 113. The facilities must comply with subparts C and F of this part regarding all other potential hazards and must comply with subparts A and B of this part.

(c) Subpart C of this part does not apply to activities of a facility that are subject to section 419 of the Federal Food, Drug, and Cosmetic Act (Standards for Produce Safety).

(d) Except as provided in subpart D of this part, qualified facilities are exempt from subpart C of this part if they comply with the requirements in § 507.7.

(e) Subpart C of this part does not apply to on-farm packing or holding of animal food by a small or very small business if the only packing and holding activities subject to section 418 of the Federal Food, Drug, and Cosmetic Act that the business conducts are the following low-risk packing or holding activity/animal food combinations on animal food not grown, raised, or consumed on that farm mixed-type facility or another farm or farm mixed-type facility under the same ownership:

(1) Conveying, weighing, sorting, culling, or grading (incidental to storing):

(i) Grain (e.g., barley, corn, rice, oat, sorghum, triticale, wheat);

(ii) Oilseed (e.g., cottonseed, linseed, rapeseed, soybean, sunflower);

(iii) Grain or oilseed byproducts;

(iv) Forage (e.g., hay or ensiled material); or

(v) Other plants or plant byproducts (e.g., almond, peanut, or soybean hulls, citrus, other fruit including culled fruit, potatoes, or other vegetables including culled vegetables).

(2) Storing:

(i) Dried grain;

(ii) Dried oilseed;

(iii) Byproducts of dried grain or dried oilseed;

(iv) Forage; or

(v) Other plants or plant byproducts.

(3) Packing:

(i) Grain;

(ii) Oilseed;

(iii) Grain or oilseed byproducts;

(iv) Forage; or

(v) Other plants or plant byproducts.

(4) Mixing (incidental to packing or storing):

(i) Grain, whole; or

(ii) Forage.

(f) Subpart C does not apply to on-farm low-risk manufacturing/processing activities conducted by a small or very small business if the only manufacturing/processing activities subject to section 418 of the Federal Food, Drug, and Cosmetic Act that the business conducts consists of the following:

(1) When conducted on a farm mixed-typed facility's own raw agriculture commodities as defined in section 201(r) of the Federal Food, Drug, and Cosmetic Act, (those grown or raised on that farm mixed-type facility or another farm/farm mixed-typed facility under the same ownership) for distribution into commerce:

(i) Cracking, crimping, or flaking:

(A) Grain (e.g., barley, corn, rice, oat, sorghum, triticale, wheat);

(B) Oilseed (e.g., cotton seed, linseed, rapeseed, soybean, sunflower); or

(C) Grain or oilseed byproducts.

(ii) Crushing, grinding, milling, pulverizing, or dry rolling:

(A) Grain;

(B) Oilseed;

(C) Grain or oilseed byproducts;

(D) Forage (e.g., hay or ensiled material); or

(E) Other plants or plant byproducts (e.g., such as almond, peanut, or soybean hulls, citrus, other fruit including culled fruit, potatoes, or other vegetables including culled vegetables).

(iii) Making silage.

(iv) Chopping or shredding hay.

(v) Extracting (mechanical) or wet rolling:

(A) Grain; or

(B) Oilseed.

(2) When conducted on animal food other than the farm mixed-typed facility's own raw agriculture commodities for distribution into commerce:

(i) Cracking, crimping, flaking, or shelling:

(A) Grain (e.g., barley, corn, rice, oat, sorghum, triticale, wheat);

(B) Oilseed (e.g., cotton seed, linseed, rapeseed, soybean, sunflower); or

(C) Grain or oilseed byproducts.

(ii) Crushing, grinding, milling, pulverizing, or dry rolling:

(A) Grain;

(B) Oilseed;

(C) Grain or oilseed byproducts;

(D) Forage (e.g., hay or ensiled material); or

(E) Other plants or plant byproducts (e.g., such as almond, peanut, or soybean hulls, citrus, other fruit including culled fruit, potatoes, or other vegetables including culled vegetables).

(iii) Making silage.

(iv) Chopping or shredding hay.

(v) Extracting (mechanical) or wet rolling:

(A) Grain; or

(B) Oilseed.

(vi) Labeling:

(A) Grain whole; or

(B) Oilseed whole.

(vii) Sifting, separating, or sizing:

(A) Grain;

(B) Oilseed;

(C) Grain or oilseed byproducts; or

(D) Other plants or plant byproducts.

(g) Subpart C of this part does not apply to facilities that are solely engaged in the storage of raw agricultural commodities (other than fruits and vegetables) intended for further distribution or processing.

(h) Subpart B of this part does not apply to the holding or transportation of one or more raw agricultural commodities as defined in section 201(r) of the Federal Food, Drug, and Cosmetic Act.

§ 507.7 Requirements that apply to a qualified facility.

(a) A qualified facility is exempt from subpart C of this part provided that for the calendar year in which it is to be considered a qualified facility, the facility has submitted to FDA documentation that:

(1) Demonstrates the facility is a qualified facility as defined in § 507.3. For the purpose of determining whether a facility satisfies the definition of qualified facility, the baseline year for calculating the adjustment for inflation is 2011; and

(2)(i) Demonstrates the owner, operator, or agent in charge of the facility has identified the potential hazards associated with the animal food being manufactured, processed, packed, or held at the facility, is implementing preventive controls to address the hazards, and is monitoring the performance of the preventive controls to ensure that such controls are effective; or

(ii) Demonstrates the facility is in compliance with state, local, county, or other applicable non-Federal food safety law. This documentation may include inspection reports, certification by an appropriate agency (such as a State department of agriculture), or other documentation deemed appropriate by FDA.

(b) The documentation required by paragraph (a) of this section must be submitted to FDA by any one of the following means:

(1) To submit electronically, go to *http://www.access.fda.gov* and follow the instructions. This Web site is available from wherever the Internet is accessible, including libraries, copy centers, schools, and Internet cafes. FDA encourages electronic submission.

(2) To submit documents in a paper format or in an electronic format on a CD–ROM, mail these to the U.S. Food and Drug Administration, ATTN: Qualified Facility Coordinator, 10903 New Hampshire Ave., Silver Spring, MD 20993. We recommend that an owner, operator, or agent in charge of a facility submit by mail only if the facility does not have reasonable access to the Internet.

(c) The documentation required by paragraph (a) of this section must be:

(1) Submitted to FDA initially within 90 days of the applicable compliance date of this part; and

(2) Resubmitted at least every 2 years, or whenever there is a material change to the information described in paragraph (a) of this section. For the purpose of this section, a material change is one that changes whether or not a facility is a "qualified facility".

(d) A qualified facility that does not submit documentation under paragraph (a)(2)(i) of this section must provide notification to consumers as to the name and complete business address (the street address, city, state, and ZIP code for domestic facilities, and comparable full address information for foreign facilities) of the facility where the animal food was manufactured or processed as follows:

(1) Such notification must appear in a prominent and conspicuous location on the label for animal food required to bear a package label under any other provision of the Federal Food, Drug, and Cosmetic Act.

(2) For animal food that is not required to bear a food packaging label, the notification must appear prominently and conspicuously, at the point of purchase, on a label, poster, sign, placard, or documents delivered contemporaneously with the food in the normal course of business, or in an electronic notice, in the case of Internet sales.

(e) A qualified facility must maintain those records relied upon to support the documentation required by § 507.7(a)(2). These records are subject to the requirements of subpart F of this part.

§ 507.10 Applicability of subpart C to a facility solely engaged in the storage of packaged animal food that is not exposed to the environment.

(a) Subpart C of this part does not apply to a facility solely engaged in the storage of packaged animal food that is not exposed to the environment and does not require time/temperature control to ensure the safety of the animal food.

(b) A facility solely engaged in the storage of packaged animal food that is not exposed to the environment but requires time/temperature control is subject to the modified requirements in § 507.48.

Subpart B—Current Good Manufacturing Practice

§ 507.14 Personnel.

(a) Plant management must take all reasonable measures and precautions to ensure that:

(1) Any person who, by his own acknowledgement, by medical examination, or by supervisory observation, is shown to have, or appears to have any illness, open skin lesion, or other source of abnormal microbial contamination by which there is a reasonable possibility of animal food, animal food-contact surfaces, or animal food-packaging materials becoming contaminated, is excluded from any operations which may be expected to result in such contamination until the condition is resolved;

(2) Personnel have been instructed to report such health conditions to their supervisors;

(3) All persons working in direct contact with animal food, animal food-contact surfaces, and animal food-packaging materials conform to hygienic practices while on duty to the extent necessary to protect against contamination of animal food. The methods for maintaining cleanliness include:

(i) Maintaining adequate personal cleanliness;

(ii) Washing hands thoroughly (and sanitizing if necessary to protect against contamination with undesirable microorganisms) in an adequate hand-washing facility before starting work and at any other time when the hands may have become soiled or contaminated;

(iii) Removing all unsecured jewelry and other objects that might fall into animal food, equipment, or containers;

(iv) Storing clothing or other personal belongings in areas other than where animal food is exposed or where equipment or utensils are washed; and

(v) Taking any other necessary precautions to protect against contamination of animal food, animal food-contact surfaces, or animal food-packaging materials with microorganisms or foreign substances.

(b) Personnel responsible for identifying sanitation failures or animal food contamination should have a background of education or experience, or a combination thereof, to provide a level of competency necessary for production of clean and safe animal food. Animal food handlers and supervisors should receive appropriate training in proper food handling techniques and food-protection principles and should be informed of the danger of poor personal hygiene and unsanitary practices.

(c) Responsibility for ensuring compliance by all personnel with all requirements of this subpart must be clearly assigned to competent supervisory personnel.

§ 507.17 Plant and grounds.

(a) The grounds about an animal food plant under the control of the operator must be kept in a condition that will protect against the contamination of animal food. The methods for adequate maintenance of grounds must include:

(1) Properly storing equipment, removing litter and waste, and cutting weeds or grass within the immediate vicinity of the plant that may constitute an attractant, breeding place, or harborage for pests;

(2) Maintaining roads, yards, and parking lots so that they do not constitute a source of contamination in areas where animal food is exposed;

(3) Adequately draining areas that may contribute to contamination of animal food by seepage, foot-borne filth, or providing a breeding place for pests; and

(4) Treating and disposing of waste so that it does not constitute a source of contamination in areas where animal food is exposed. If the plant grounds are bordered by grounds not under the operator's control and not maintained in the manner described in paragraph (a)(1) through (a)(3) of this section, care must be exercised in the plant by inspection, extermination, or other means to exclude pests, dirt, and filth that may be a source of animal food contamination.

(b) The plant's buildings and structures must be suitable in size, construction, and design to facilitate maintenance and sanitary operations for animal food-production purposes (i.e., manufacturing, processing, packing, and holding). The plant must:

(1) Provide sufficient space for such placement of equipment and storage of materials as is necessary for the maintenance of sanitary operations and the production of safe animal food.

(2) Permit the taking of proper precautions to reduce the potential for contamination of animal food, animal food-contact surfaces, or animal food-packaging materials with microorganisms, chemicals, filth, and other extraneous material. The potential for contamination may be reduced by adequate food safety controls and operating practices or effective design, including the separation of operations in which contamination is likely to occur, by one or more of the following means: Location, time, partition, air flow, enclosed systems, or other effective means.

(3) Permit the taking of proper precautions to protect animal food in outdoor bulk vessels by any effective means, including:

(i) Using protective coverings;

(ii) Controlling areas over and around the vessels to eliminate harborages for pests;

(iii) Checking on a regular basis for pests and pest infestation; and

(iv) Skimming fermentation vessels, as necessary.

(4) Be constructed in such a manner that floors, walls, and ceilings may be adequately cleaned and kept clean and kept in good repair; that drip or condensate from fixtures, ducts, and pipes does not contaminate animal food, animal food-contact surfaces, or animal food-packaging materials; and that aisles or working spaces are provided between equipment and walls and are adequately unobstructed and of adequate width to permit employees to perform their duties and to protect against contaminating animal food, animal food-contact surfaces, or animal food-packaging materials.

(5) Provide adequate lighting in hand-washing areas, toilet rooms, areas where animal food is examined, processed, or stored, and areas where equipment or utensils are cleaned; and provide safety-type light bulbs, fixtures, and skylights, or other glass items suspended over exposed animal food in any step of preparation, or otherwise protect against animal food contamination in case of glass breakage.

(6) Provide adequate ventilation or control equipment to minimize odors and vapors (including steam and noxious fumes) in areas where they may contaminate animal food; and locate and operate fans and other air-blowing equipment in a manner that minimizes the potential for contaminating animal food, animal food-packaging materials, and animal food-contact surfaces.

(7) Provide, where necessary, adequate screening or other protection against pests.

§ 507.19 Sanitary operations.

(a) Buildings, fixtures, and other physical facilities of the plant must be maintained in a sanitary condition and must be kept in repair sufficient to prevent animal food from becoming adulterated. Cleaning and sanitizing of utensils and equipment must be conducted in a manner that protects against contamination of animal food, animal food-contact surfaces, or animal food-packaging materials.

(b) Cleaning compounds and sanitizing agents must be free from undesirable microorganisms and must be safe and adequate under the conditions of use. Compliance with this requirement may be verified by any effective means, including purchase of these substances under a supplier's guarantee or certification or examination of these substances for contamination.

(c) The following applies to toxic materials:

(1) Only the following toxic materials may be used or stored in a plant where animal food is processed or exposed:

(i) Those required to maintain clean and sanitary conditions;

(ii) Those necessary for use in laboratory testing procedures;

(iii) Those necessary for plant and equipment maintenance and operation; and

(iv) Those necessary for use in the plant's operations.

(2) Toxic cleaning compounds, sanitizing agents, and pesticide chemicals must be identified, held, and stored in a manner that protects against contamination of animal food, animal food-contact surfaces, or animal food-packaging materials.

(d) Effective measures must be taken to exclude pests from the manufacturing, processing, packing, and holding areas and to protect against the contamination of animal food on the premises by pests. The use of insecticides or rodenticides is permitted only under precautions and restrictions that will protect against the contamination of animal food, animal food-contact surfaces, and animal food-packaging materials.

(e) All animal food-contact surfaces, including utensils and animal food-contact surfaces of equipment, must be cleaned as frequently as necessary to protect against contamination of animal food.

(1) Animal food-contact surfaces used for manufacturing, processing or holding low-moisture animal food must be in a clean, dry, sanitary condition at the time of use. When the surfaces are wet-cleaned, they must, when necessary, be sanitized and thoroughly dried before subsequent use.

(2) In wet processing, when cleaning is necessary to protect against the introduction of microorganisms into animal food, all animal food-contact surfaces must be cleaned and sanitized before use and after any interruption during which the animal food-contact surfaces may have become contaminated. Where equipment and utensils are used in a continuous production operation, the utensils and animal food-contact surfaces of the equipment must be cleaned and sanitized as necessary.

(3) Single-service articles (such as utensils intended for one-time use, paper cups, and paper towels) should be stored in appropriate containers and must be handled, dispensed, used, and disposed of in a manner that protects against contamination of animal food, animal food-contact surfaces, or animal food-packaging materials.

(f) Non-animal food-contact surfaces of equipment used in the operation of an animal food plant should be cleaned in a manner and as frequently as necessary to protect against contamination of animal food, animal food-contact surfaces, and animal food-packaging materials.

(g) Cleaned and sanitized portable equipment with animal food-contact surfaces and utensils should be stored in a location and manner that protects animal food-contact surfaces from contamination.

§ 507.20 Sanitary facilities and controls.

(a) The water supply must be sufficient for the operations intended and must be derived from an adequate source. Any water that contacts animal food, animal food-contact surfaces, or animal food-packaging materials must be safe and of adequate sanitary quality. Running water at a suitable temperature, and under pressure as needed, must be provided in all areas where required for the processing of animal food, for the cleaning of equipment, utensils, and animal food-packaging materials, or for employee sanitary facilities.

(b) Plumbing must be of adequate size and design and adequately installed and maintained to:

(1) Carry sufficient quantities of water to required locations throughout the plant;

(2) Properly convey sewage and liquid disposable waste from the plant;

(3) Avoid constituting a source of contamination to animal food, water supplies, equipment, or utensils or creating an unsanitary condition;

(4) Provide adequate floor drainage in all areas where floors are subject to flooding-type cleaning or where normal operations release or discharge water or other liquid waste on the floor; and

(5) Provide that there is not backflow from, or cross-connection between, piping systems that discharge waste water or sewage and piping systems that carry water for animal food or animal food manufacturing.

(c) Sewage must be disposed of through an adequate sewerage system or through other adequate means.

(d) Each plant must provide its employees with adequate, readily accessible toilet facilities. Toilet facilities must be kept clean and must not be a potential source of contamination of animal food, animal food-contact surfaces, or animal food-packaging materials.

(e) Each plant must provide hand-washing facilities designed to ensure that an employee's hands are not a source of contamination of animal food, animal food-contact surfaces, or animal food-packaging materials, by providing facilities that are adequate, convenient, and furnish running water at a suitable temperature.

(f) Rubbish must be conveyed, stored, and disposed of in a way to minimize the development of odor, minimize the potential for the waste becoming an attractant and harborage or breeding place for pests, and protect against contamination of animal food, animal food-contact surfaces, animal food-packaging materials, water supplies, and ground surfaces.

§ 507.22 Equipment and utensils.

(a)(1) All plant equipment and utensils must be designed and of such material and workmanship to be adequately cleanable, and must be properly maintained;

(2) The design, construction, and use of equipment and utensils must preclude the adulteration of animal food with lubricants, fuel, metal fragments, contaminated water, or any other contaminants;

(3) All equipment should be installed and maintained in such a way to facilitate the cleaning of the equipment and all adjacent spaces;

(4) Animal food-contact surfaces must be made of materials that resist corrosion when in contact with animal food;

(5) Animal food-contact surfaces must be made of nontoxic materials and designed to withstand the environment of their intended use and the action of animal food, and, if applicable, the action of cleaning compounds and sanitizing agents; and

(6) Animal food-contact surfaces must be maintained to protect animal food from being contaminated.

(b) Seams on animal food-contact surfaces must be maintained so as to minimize accumulation of food particles, dirt, and organic matter, and thus minimize the opportunity for growth of microorganisms.

(c) Equipment in the animal food manufacturing or handling area that does not come into contact with animal food must be constructed in such a way that it can be kept in a clean condition.

(d) Holding, conveying, and manufacturing systems, including gravimetric, pneumatic, closed, and automated systems, must be of a design and construction that enables them to be maintained in an appropriate sanitary condition.

(e) Each freezer and cold storage compartment used to store and hold animal food capable of supporting growth of microorganisms must be fitted with an indicating thermometer, temperature-measuring device, or temperature-recording device installed to show the temperature accurately within the compartment.

(f) Instruments and controls used for measuring, regulating, or recording temperatures, pH, a_w, or other conditions that control or prevent the growth of undesirable microorganisms in animal food must be accurate and precise and adequately maintained, and adequate in number for their designated uses.

(g) Compressed air or other gases mechanically introduced into animal food or used to clean animal food-contact surfaces or equipment must be treated in such a way that animal food is not contaminated.

§ 507.25 Processes and controls.

(a) Plant management must ensure that:

(1) All operations in the manufacturing, processing, packing, and holding of animal food (including operations directed to receiving, inspecting, transporting, and segregating) are conducted in accordance with adequate sanitation principles;

(2) Containers holding animal food, raw materials, or ingredients are labeled to accurately identify the contents;

(3) The labeling for the finished animal food product contains the specific information and instructions needed so the food can be safely used for the intended animal species;

(4) Appropriate quality control operations are employed so that animal food-packaging materials are safe and suitable;

(5) The overall sanitation of the plant is under the supervision of one or more competent individuals assigned responsibility for this function;

(6) All reasonable precautions are taken so that production procedures do not contribute to contamination from any source;

(7) Chemical, microbial, or extraneous-material testing procedures are used where necessary to identify sanitation failures or possible animal food contamination; and

(8) All animal food that has become contaminated to the extent that it is adulterated is rejected, or if permissible, treated or processed to eliminate the contamination.

(b) Raw materials and ingredients:

(1) Must be inspected and segregated or otherwise handled as necessary to ensure that they are clean and suitable for processing into animal food and must be stored under conditions that will protect against contamination and minimize deterioration. In addition:

(i) Raw materials must be washed or cleaned as necessary to remove soil or other contamination;

(ii) Water used for washing, rinsing, or conveying animal food must be safe and of adequate sanitary quality;

(iii) Water may be reused for washing, rinsing, or conveying animal food if it does not increase the level of contamination of the animal food; and

(iv) Containers and carriers of raw materials should be inspected on receipt to ensure that their condition has not contributed to contamination or deterioration of animal food.

(2) Must not contain levels of microorganisms that may render the food injurious to the health of animals or humans, or they must be treated (e.g., heat) during manufacturing operations so that they no longer contain levels that would cause the product to be adulterated;

(3) Susceptible to contamination with aflatoxin or other natural toxins must comply with current FDA regulations for poisonous or deleterious substances before these materials or ingredients are incorporated into finished animal food;

(4) Including rework, must be held in bulk, or in containers designed and constructed in a way that protects against contamination, and must be held at a temperature and relative humidity and in a manner that prevents the animal food from becoming adulterated. Material scheduled for rework must be identified as such;

(5) If frozen, must be kept frozen. If thawing is required prior to use, it must be done in a manner that prevents the raw materials and ingredients from becoming adulterated; and

(6) Whether liquid or dry, received and stored in bulk form must be held in a manner that protects against contamination.

(c) For the purposes of manufacturing operations, the following apply:

(1) Equipment, utensils, and finished animal food containers must be maintained in an acceptable condition through appropriate cleaning and sanitizing, as necessary. When necessary, equipment must be taken apart for thorough cleaning;

(2) All animal food manufacturing, processing, packing, and holding must be conducted under such conditions and controls as are necessary to minimize the potential for the growth of microorganisms or for the contamination of animal food;

(3) Animal food that can support the rapid growth of undesirable microorganisms must be held at temperatures that will prevent the animal food from becoming adulterated during manufacturing, processing, packing, and holding;

(4) Measures taken to destroy or prevent the growth of undesirable microorganisms, such as sterilizing, irradiating, pasteurizing, cooking, freezing, refrigerating, controlling pH, or controlling a_w, must be adequate under the conditions of manufacture, handling, and distribution to prevent animal food from being adulterated;

(5) Work-in-process and rework must be handled in a manner that protects against contamination and the growth of undesirable microorganisms;

(6) Effective measures must be taken to protect finished animal food from contamination by raw materials, ingredients, or refuse. When raw materials, ingredients, or refuse are unprotected, they must not be handled simultaneously in a receiving, loading, or shipping area if that handling could result in contaminated animal food. Animal food transported by conveyor must be protected against contamination as necessary;

(7) Equipment, containers, and utensils used to convey, hold, or store raw materials, work-in-process, rework, or animal food must be constructed, handled, and maintained during manufacturing, processing, packing, or holding in a manner that protects against contamination of animal food;

(8) Effective measures must be taken to protect against the inclusion of metal or other extraneous material in animal food;

(9) Adulterated animal food, raw materials, and ingredients must be disposed of in a manner that protects against the contamination of other animal food or, if the adulterated animal food, raw materials, or ingredients are capable of being reconditioned, they must be reconditioned using a method that has been proven to be effective;

(10) Steps such as washing, peeling, trimming, cutting, sorting and inspecting, mashing, dewatering, cooling, shredding, extruding, drying, defatting, and forming must be performed in a way that protects animal food against contamination. Animal food should be protected from contaminants that may drip, drain, or be drawn into the animal food;

(11) Heat blanching, when required in the preparation of animal food, should be effected by heating the animal food to the required temperature, holding it at this temperature for the required time, and then either rapidly cooling the animal food or passing it to subsequent manufacturing without delay. Thermophilic growth and contamination in blanchers should be minimized by the use of adequate operating temperatures and by periodic cleaning;

(12) Batters, breading, sauces, gravies, dressings, and other similar preparations must be treated or maintained in such a manner that they are protected against contamination;

(13) Filling, assembling, packaging, and other operations must be performed in such a way that the animal food is protected against contamination and growth of undesirable microorganisms;

(14) Animal food, including dry mixes, nuts, intermediate moisture animal food, and dehydrated animal food, that relies on the control of a_w for preventing the growth of undesirable microorganisms must be processed to and maintained at a safe moisture level;

(15) Animal food that relies principally on the control of pH for preventing the growth of undesirable microorganisms must be monitored and maintained at the appropriate pH; and

(16) When ice is used in contact with animal food, it must be made from water that is safe and of adequate sanitary quality, and must be used only if it has been manufactured in accordance with current good manufacturing practice as outlined in this part.

§ 507.28 Warehousing and distribution.

Storage and transportation of animal food must be conducted under conditions that will protect against biological, chemical, physical, and radiological contamination of animal food as well as against deterioration of the animal food and the container.

Subpart C—Hazard Analysis and Risk-Based Preventive Controls

§ 507.30 Requirement for a food safety plan.

(a) The owner, operator, or agent in charge of a facility must prepare, or have prepared, and implement a written food safety plan.

(b) The written food safety plan must be prepared by (or its preparation overseen by) a qualified individual.

(c) The written food safety plan must include:

(1) The hazard analysis as required by § 507.33;

(2) The preventive controls as required by § 507.36;

(3) The recall plan as required by § 507.38;

(4) The procedures and the frequency with which these procedures will be conducted for monitoring the performance of the preventive controls as required by § 507.39;

(5) The corrective action procedures as required by § 507.42; and

(6) The verification procedures and the frequency with which they will be performed as required by § 507.45.

§ 507.33 Hazard analysis.

(a) The owner, operator, or agent in charge of a facility must identify and evaluate known or reasonably foreseeable hazards for each type of animal food manufactured, processed, packed, or held at the facility to determine whether there are hazards that are reasonably likely to occur and develop a written hazard analysis.

(b) The hazard analysis must consider hazards that may occur naturally or may be unintentionally introduced including:

(1) Biological hazards, including microbiological hazards such as parasites, environmental pathogens, and other microorganisms of animal or human health significance;

(2) Chemical hazards, including substances such as pesticide and drug residues, natural toxins, decomposition, unapproved food or color additives, and nutrient imbalances;

(3) Physical hazards; and

(4) Radiological hazards.

(c) The hazard analysis must contain an evaluation of the hazards identified in paragraph (b) of this section to determine whether the hazards are reasonably likely to occur, including an assessment of the severity of the illness or injury if the hazard were to occur.

(d) The hazard analysis must consider the effect of the following on the safety of the finished animal food:

(1) The formulation of the animal food;

(2) The condition, function, and design of the facility and equipment;

(3) Raw materials and ingredients;

(4) Transportation practices;

(5) Manufacturing/processing procedures;

(6) Packaging activities and labeling activities;

(7) Storage and distribution;

(8) Intended or reasonably foreseeable use;

(9) Sanitation, including employee hygiene; and

(10) Any other relevant factors.

§ 507.36 Preventive controls for hazards that are reasonably likely to occur.

For hazards identified in the hazard analysis as reasonably likely to occur:

(a) The owner, operator, or agent in charge of a facility must identify and implement preventive controls, including at critical control points, if any, to provide assurances that hazards identified in the hazard analysis as reasonably likely to occur will be significantly minimized or prevented and the animal food manufactured, processed, packed, or held by such facility will not be adulterated under section 402 of the Federal Food, Drug, and Cosmetic Act.

(b) Preventive controls must be written.

(c) Preventive controls must include, as appropriate to the facility and animal food:

(1) Parameters associated with the control of the hazard, such as parameters associated with heat processing, irradiating, and refrigerating animal foods; and

(2) The maximum or minimum value, or combination of values, to which any biological, chemical, physical, or radiological parameter must be controlled to significantly minimize or prevent a hazard that is reasonably likely to occur.

(d) Preventive controls must include, as appropriate:

(1) Process controls that include those procedures, practices, and processes performed on an animal food during manufacturing/processing that are employed to significantly minimize or prevent hazards that are reasonably likely to occur;

(2) Sanitation controls:

(i) Where necessary to significantly minimize or prevent hazards that are reasonably likely to occur, procedures for the:

(A) Cleanliness of animal food-contact surfaces, including animal food-contact surfaces of utensils and equipment; and

(B) Prevention of cross-contamination from insanitary objects and from personnel to animal food, animal food packaging material, and other animal food-contact surfaces and from raw product to processed product.

(ii) The owner, operator, or agent in charge must take action to correct, in a timely manner, conditions and practices that are not consistent with the procedures in paragraph (d)(2)(i)(A) or (d)(2)(i)(B) of this section.

(iii) The owner, operator, or agent in charge of the facility is not required to follow the corrective actions described in § 507.42(a) and (b) when the owner, operator, or agent in charge of a facility takes action, in accordance with paragraph (d)(2)(ii) of this section, to correct conditions and practices that are not consistent with the procedures in paragraph (d)(2)(i)(A) or (d)(2)(i)(B) of this section.

(iv) All corrective actions taken in accordance with paragraph (d)(2)(ii) of this section must be documented in records that are subject to verification in accordance with § 507.45(b)(2) and records review in accordance with § 507.45(c)(1)(i) and (c)(2).

(3) A recall plan as required by § 507.38; and

(4) Any other controls necessary to satisfy the requirements of paragraph (a) of this section.

(e)(1) Except as provided by paragraph (e)(2) of this section, the preventive controls required under this section are subject to:

(i) Monitoring as required by § 507.39;

(ii) Corrective actions as required by § 507.42; and

(iii) Verification as required by § 507.45.

(2) The recall plan established in § 507.38 is not subject to the requirements of paragraph (e)(1) of this section.

§ 507.38 Recall plan for animal food with a hazard that is reasonably likely to occur.

(a) The owner, operator, or agent in charge of a facility must develop a written recall plan for animal food with a hazard that is reasonably likely to occur and assign responsibility for performing all actions in the plan.

(b) The written recall plan must include procedures for:

(1) Directly notifying direct consignees about the animal food being recalled, including how to return or dispose of the affected animal food;

(2) Notifying the public about any hazard presented by the animal food when appropriate to protect animal and human health;

(3) Conducting effectiveness checks (as described in part 7 of this chapter) to verify the recall has been carried out; and

(4) The proper disposition (e.g., destroying, reprocessing, or diverting to another use that would not present a safety concern) of the recalled animal food.

§ 507.39 Monitoring.

(a) The owner, operator, or agent in charge of a facility must establish and implement written procedures for monitoring the preventive controls. These procedures must include:

(1) What preventive controls will be monitored;

(2) Who will perform the monitoring;

(3) How the monitoring will be performed;

(4) What parameter will be measured, if applicable;

(5) Frequency with which the monitoring will be performed; and

(6) Any additional information needed to ensure appropriate monitoring of the preventive controls.

(b) The owner, operator, or agent in charge of a facility must monitor the preventive controls with sufficient frequency to provide assurance that the preventive controls are consistently performed.

(c) Monitoring of preventive controls in accordance with this section must be documented in records that are subject to verification in accordance with § 507.45(b)(1) and records review in accordance with § 507.45(c)(1)(i) and (c)(2).

§ 507.42 Corrective actions.

(a) The owner, operator, or agent in charge of a facility must establish and implement written corrective action procedures that must be taken if preventive controls are not properly implemented. The corrective active procedures must describe the steps to be taken to ensure:

(1) Appropriate action is taken to identify and correct a problem with implementation of a preventive control to reduce the likelihood that the problem will recur;

(2) All affected animal food is evaluated for safety; and

(3) All affected animal food is prevented from entering into commerce if the owner, operator, or agent in charge of the facility cannot ensure the affected animal food is not adulterated under

section 402 of the Federal Food, Drug, and Cosmetic Act.

(b) If a preventive control is not properly implemented and a specific corrective action procedure has not been established, or a preventive control is found to be ineffective, the owner, operator, or agent in charge of a facility must:

(1) Take corrective action to identify and correct the problem to reduce the likelihood that the problem will recur;

(2) Evaluate all affected animal food for safety;

(3) As necessary, prevent affected animal food from entering commerce as would be done following the corrective action procedure under paragraph (a)(3) of this section; and

(4) Reanalyze the food safety plan in accordance with § 507.45(e) to determine whether modification of the food safety plan is required.

(c) When corrective actions are taken, they must be documented in written records. These records are subject to verification in accordance with § 507.45(b)(2) and records review in accordance with § 507.45(c)(1)(i) and (c)(2).

§ 507.45 Verification.

(a) Except as provided by paragraph (a)(3) of this section, the owner, operator, or agent in charge of a facility must validate that the preventive controls identified and implemented in accordance with § 507.36 to control the hazards identified in the hazard analysis as reasonably likely to occur are adequate to do so. The validation of the preventive controls:

(1) Must be performed (or overseen) by a qualified individual:

(i) Prior to implementation of the food safety plan or, when necessary, during the first 6 weeks of production; and

(ii) Whenever a reanalysis of the food safety plan reveals the need to do so;

(2) Must include collecting and evaluating scientific and technical information (or, when such information is not available or is insufficient, conducting studies) to determine whether the preventive controls, when properly implemented, will effectively control the hazards that are reasonably likely to occur; and

(3) Need not address:

(i) The sanitation controls in § 507.36(d)(2); and

(ii) The recall plan in § 507.38.

(b) The owner, operator, or agent in charge of a facility must verify that:

(1) Monitoring is conducted as required by § 507.39;

(2) Appropriate decisions about corrective actions are being made as required by § 507.42;

(3) The preventive controls are consistently implemented and are effectively and significantly minimizing or preventing the hazards that are reasonably likely to occur; and

(4) The activities conducted must include, as appropriate to the facility and the animal food, calibration of process monitoring and verification instruments.

(c) The owner, operator, or agent in charge of a facility must verify that the preventive controls are consistently implemented and are effectively and significantly minimizing or preventing the hazards that are reasonably likely to occur by ensuring that a qualified individual is conducting (or overseeing):

(1) A review of the following records in the timeframe specified:

(i) Monitoring and corrective action records within 1 week after the records are made; and

(ii) Records of calibration of instruments within a reasonable time after the records are created.

(2) A review of the records in paragraphs (c)(1)(i) and (c)(1)(ii) of this section to ensure:

(i) The records are complete;

(ii) The activities reflected in the records occurred in accordance with the food safety plan;

(iii) The preventive controls are effective; and

(iv) Appropriate decisions were made about corrective actions.

(d) The owner, operator, or agent in charge of a facility must establish and implement written procedures, as appropriate to the facility and the animal food, for the frequency of calibrating process monitoring and verification instruments.

(e) The owner, operator, or agent in charge of a facility must:

(1) Conduct a reanalysis of the food safety plan:

(i) At least once every 3 years;

(ii) Whenever a significant change is made in the activities conducted at the facility operated by such owner, operator, or agent in charge if the change creates a reasonable potential for a new hazard or creates a significant increase in a previously identified hazard;

(iii) Whenever the owner, operator, or agent in charge becomes aware of new information about potential hazards associated with the animal food;

(iv) Whenever a preventive control is not properly implemented and a specific corrective action procedure has not been established;

(v) Whenever a preventive control is found to be ineffective; and

(vi) Whenever FDA requires a reanalysis in response to newly identified hazards and developments in scientific understanding.

(2) Complete the reanalysis and implement any additional preventive controls needed to address the hazard identified before the change in activities at the facility is operative or, when necessary, during the first 6 weeks of production;

(3) Revise the written food safety plan if a significant change is made, or document the basis for the conclusion that no additional or revised preventive controls are needed; and

(4) Ensure the reanalysis is performed (or overseen) by a qualified individual.

(f) All verification activities taken in accordance with this section must be documented in records.

§ 507.48 Modified requirements that apply to a facility solely engaged in the storage of packaged animal food that is not exposed to the environment.

(a) The owner, operator, or agent in charge of a facility solely engaged in the storage of packaged animal food that is not exposed to the environment must conduct the following activities for any such refrigerated packaged animal food that requires time/temperature control to significantly minimize or prevent the growth of, or toxin formation by, microorganisms of animal or human health significance:

(1) Establish and implement temperature controls adequate to significantly minimize or prevent the growth of, or toxin formation by, microorganisms of animal or human health significance;

(2) Monitor the temperature controls with sufficient frequency to provide assurance they are consistently performed;

(3) Take appropriate corrective actions if there is a problem with the temperature controls for such refrigerated packaged animal food to:

(i) Correct the problem and reduce the likelihood that the problem will recur;

(ii) Evaluate all affected animal food for safety; and

(iii) Prevent the animal food from entering commerce, if the owner, operator, or agent in charge of the facility cannot ensure the affected animal food is not adulterated under section 402 of the Federal Food, Drug, and Cosmetic Act;

(4) Verify that temperature controls are consistently implemented by:

(i) Calibrating temperature monitoring and recording devices;

(ii) Reviewing records of calibration within a reasonable time after the records are made; and

(iii) Reviewing records of monitoring and corrective actions taken to correct a problem with the control of temperature within a week after the records are made;

(5) Establish and maintain the following records:

(i) Records documenting the monitoring of temperature controls for any such refrigerated packaged animal food;

(ii) Records of corrective actions taken when there is a problem with the control of temperature for any such refrigerated packaged animal food; and

(iii) Records documenting the verification activities.

(b) The records that a facility must establish and maintain under paragraph (a)(5) of this section are subject to the requirements of subpart F of this part.

§ 507.50 Requirements applicable to a qualified individual.

(a) One or more qualified individuals must do or oversee the following:

(1) Prepare the food safety plan (§ 507.30));

(2) Validate the preventive controls (§ 507.45(a));

(3) Conduct a review of records for implementation and effectiveness of preventive controls and appropriateness of corrective actions (§ 507.45(c));

(4) Perform a reanalysis of the food safety plan (§ 507.45(e)).

(b) To be qualified, an individual must have successfully completed training in the development and application of risk-based preventive controls at least equivalent to that received under a standardized curriculum recognized as adequate by FDA or be otherwise qualified through job experience to develop and apply a food safety system. Job experience may qualify an individual to perform these functions if such experience has provided an individual with knowledge at least equivalent to that provided through the standardized curriculum. This individual may be, but is not required to be, an employee of the facility.

(c) All applicable training must be documented in records, including the date of the training, the type of training, and the person(s) trained.

§ 507.55 Records required for this subpart C.

(a) The owner, operator, or agent in charge of a facility must establish and maintain the following records:

(1) The written food safety plan, including the written hazard analysis, preventive controls, monitoring procedures, corrective action procedures, verification procedures, and recall plan;

(2) Records that document the monitoring of preventive controls;

(3) Records that document corrective actions;

(4) Records that document verification, including, as applicable, those related to:

(i) Validation;

(ii) Monitoring;

(iii) Corrective actions;

(iv) Calibration of process monitoring and verification instruments;

(v) Records review; and

(vi) Reanalysis; and

(5) Records that document applicable training for the qualified individual.

(b) The records that the owner, operator, or agent in charge of a facility must establish and maintain are subject to the requirements of subpart F of this part.

Subpart D—Withdrawal of an Exemption Applicable to a Qualified Facility

§ 507.60 Circumstances that may lead FDA to withdraw an exemption applicable to a qualified facility.

FDA may withdraw the exemption applicable to a qualified facility under § 507.5(d):

(a) In the event of an active investigation of a foodborne illness outbreak that is directly linked to the qualified facility; or

(b) If FDA determines that it is necessary to protect the animal or human health and prevent or mitigate a foodborne illness outbreak based on conduct or conditions associated with the qualified facility that are material to the safety of the animal food manufactured, processed, packed, or held at such facility.

§ 507.62 Issuance of an order to withdraw an exemption applicable to a qualified facility.

(a) If FDA determines that an exemption applicable to a qualified facility under § 507.5(d) should be withdrawn, any officer or qualified employee of FDA may issue an order to withdraw the exemption.

(b) An FDA District Director in whose district the qualified facility is located (or, in the case of a foreign facility, the Director of the Division of Compliance in the Center for Veterinary Medicine), or an FDA official senior to such Director, must approve an order to withdraw the exemption.

(c) FDA must issue an order to withdraw the exemption to the owner, operator, or agent in charge of the facility.

(d) FDA must issue an order to withdraw the exemption in writing, signed and dated by the officer or qualified employee of FDA who is issuing the order.

§ 507.65 Contents of an order to withdraw an exemption applicable to a qualified facility.

An order to withdraw an exemption applicable to a qualified facility under § 507.5(d) must include the following information:

(a) The date of the order;

(b) The name, address, and location of the qualified facility;

(c) A brief, general statement of the reasons for the order, including information relevant to:

(1) An active investigation of a foodborne illness outbreak that is directly linked to the facility; or

(2) Conduct or conditions associated with a qualified facility that are material to the safety of the animal food manufactured, processed, packed, or held at such facility.

(d) A statement that the facility must comply with subpart C of this part on the date that is 60 calendar days after the date of the order;

(e) The text of section 418(l) of the Federal Food, Drug, and Cosmetic Act and of this subpart D;

(f) A statement that any informal hearing on an appeal of the order must be conducted as a regulatory hearing under part 16 of this chapter, with certain exceptions described in § 507.73;

(g) The mailing address, telephone number, email address, and facsimile number of the FDA district office and the name of the FDA District Director in whose district the facility is located (or, in the case of a foreign facility, the same information for the Director of the Division of Compliance in the Center for Veterinary Medicine); and

(h) The name and the title of the FDA representative who approved the order.

§ 507.67 Compliance with, or appeal of, an order to withdraw an exemption applicable to a qualified facility.

(a) The owner, operator, or agent in charge of a qualified facility that receives an order under § 507.60 to withdraw an exemption applicable to that facility under § 507.5(d) must either:

(1) Comply with applicable requirements of this part within 60 calendar days of the date of the order; or

(2) Appeal the order within 10 calendar days of the date of the order in accordance with the requirements of § 507.69.

(b) Submission of an appeal, including submission of a request for an informal hearing, will not operate to delay or stay any administrative action, including enforcement action by FDA, unless the Commissioner, as a matter of discretion, determines that delay or a stay is in the public interest.

(c) If the owner, operator, or agent in charge of the qualified facility appeals the order, and FDA confirms the order, the owner, operator, or agent in charge of the facility must comply with applicable requirements of this part within 60 calendar days of the date of the order.

§ 507.69 Procedure for submitting an appeal.

(a) To appeal an order to withdraw an exemption applicable to a qualified facility under § 507.5(d), the owner, operator, or agent in charge of the facility must:

(1) Submit the appeal in writing to the FDA District Director in whose district the facility is located (or, in the case of a foreign facility, the Director of the Division of Compliance in the Center for Veterinary Medicine), at the mailing address, email address, or facsimile number identified in the order within 10 calendar days of the date of the order;

(2) Respond with particularity to the facts and issues contained in the order, including any supporting documentation upon which the owner, operator, or agent in charge of the facility relies.

(b) In a written appeal of the order withdrawing an exemption provided under § 507.5(d), the owner, operator, or agent in charge of the facility may include a written request for an informal hearing as provided in § 507.71.

§ 507.71 Procedure for requesting an informal hearing.

(a) If the owner, operator, or agent in charge of the facility appeals the order, the owner, operator, or agent in charge of the facility:

(1) May request an informal hearing; and

(2) Must submit any request for an informal hearing together with its written appeal submitted in accordance with § 507.69 within 10 calendar days of the date of the order.

(b) A request for an informal hearing may be denied, in whole or in part, if the presiding officer determines that no genuine and substantial issue of material fact has been raised by the material submitted. If the presiding officer determines that a hearing is not justified, written notice of the determination will be given to the owner, operator, or agent in charge of the facility explaining the reason for the denial.

§ 507.73 Requirements applicable to an informal hearing.

If the owner, operator, or agent in charge of the facility requests an informal hearing, and FDA grants the request:

(a) The hearing will be held within 10 calendar days after the date the appeal is filed or, if applicable, within a timeframe agreed upon in writing by the owner, operator, or agent in charge of the facility and FDA.

(b) The presiding officer may require that a hearing conducted under this subpart be completed within 1 calendar day, as appropriate.

(c) FDA must conduct the hearing in accordance with part 16 of this chapter, except that:

(1) The order withdrawing an exemption under §§ 507.62 and 507.65, rather than the notice under § 16.22(a) of this chapter, provides notice of opportunity for a hearing under this section and is part of the administrative record of the regulatory hearing under § 16.80(a) of this chapter.

(2) A request for a hearing under this subpart must be addressed to the FDA District Director (or, in the case of a foreign facility, the Director of the Division of Compliance in the Center for Veterinary Medicine) as provided in the order withdrawing an exemption.

(3) Section 507.75, rather than § 16.42(a) of this chapter, describes the FDA employees who preside at hearings under this subpart.

(4) Section 16.60(e) and (f) of this chapter does not apply to a hearing under this subpart. The presiding officer must prepare a written report of the hearing. All written material presented at the hearing will be attached to the report. The presiding officer must include as part of the report of the hearing a finding on the credibility of witnesses (other than expert witnesses) whenever credibility is a material issue, and must include a proposed decision, with a statement of reasons. The hearing participant may review and comment on the presiding officer's report within 2 calendar days of issuance of the report. The presiding officer will then issue the final decision.

(5) Section 16.80(a)(4) of this chapter does not apply to a regulatory hearing under this subpart. The presiding officer's report of the hearing and any comments on the report by the hearing participant under § 507.73(c)(4) are part of the administrative record.

(6) No party shall have the right, under § 16.119 of this chapter to petition the Commissioner for reconsideration or a stay of the presiding officer's final decision.

(7) If FDA grants a request for an informal hearing on an appeal of an order withdrawing an exemption, the hearing must be conducted as a regulatory hearing under part 16 of this chapter, except that § 16.95(b) does not apply to a hearing under this subpart. With respect to a regulatory hearing under this subpart, the administrative record of the hearing specified in §§ 16.80(a)(1), (a)(2), (a)(3), and (a)(5), and 507.73(c)(5) constitutes the exclusive record for the presiding officer's final decision. For purposes of judicial review under § 10.45 of this chapter, the record of the administrative proceeding consists of the record of the hearing and the presiding officer's final decision.

§ 507.75 Presiding officer for an appeal and for an informal hearing.

The presiding officer for an appeal, and for an informal hearing, must be an FDA Regional Food and Drug Director or another FDA official senior to an FDA District Director.

§ 507.77 Timeframe for issuing a decision on an appeal.

(a) If the owner, operator, or agent in charge of a facility appeals the order without requesting a hearing, the presiding officer must issue a written report that includes a final decision confirming or revoking the withdrawal by the 10th calendar day after the appeal is filed.

(b) If the owner, operator, or agent in charge of a facility appeals the order and requests an informal hearing:

(1) If FDA grants the request for a hearing and the hearing is held, the presiding officer must provide a 2 calendar day opportunity for the hearing participants to review and submit comments on the report of the hearing under § 507.73(c)(4), and must issue a final decision within 10 calendar days after the hearing is held; or

(2) If FDA denies the request for a hearing, the presiding officer must issue a final decision on the appeal confirming or revoking the withdrawal within 10 calendar days after the date the appeal is filed.

§ 507.80 Revocation of an order to withdraw an exemption applicable to a qualified facility.

An order to withdraw an exemption applicable to a qualified facility under § 507.5(d) is revoked if:

(a) The owner, operator, or agent in charge of the facility appeals the order and requests an informal hearing, FDA grants the request for an informal hearing, and the presiding officer does not confirm the order within the 10 calendar days after the hearing, or issues a decision revoking the order within that time; or

(b) The owner, operator, or agent in charge of the facility appeals the order and requests an informal hearing, FDA denies the request for an informal hearing, and FDA does not confirm the order within the 10 calendar days after the appeal is filed, or issues a decision revoking the order within that time; or

(c) The owner, operator, or agent in charge of the facility appeals the order without requesting an informal hearing, and FDA does not confirm the order within the 10 calendar days after the appeal is filed, or issues a decision revoking the order within that time.

§ 507.83 Final agency action.

Confirmation of a withdrawal order by the presiding officer is considered a final agency action for purposes of 5 U.S.C. 702.

Subpart E—[Reserved]

Subpart F—Requirements Applying to Records That Must Be Established and Maintained

§ 507.100 Records subject to the requirements of this subpart F.

(a) Except as provided by paragraphs (d) and (e) of this section, all records required by this part are subject to all requirements of this subpart F.

(b) Records required by this part are subject to the disclosure requirements under part 20 of this chapter.

(c) All records required by this part must be made promptly available to a duly authorized representative of the Secretary of Health and Human Services upon oral or written request.

(d) The requirements of § 507.106 apply only to the written food safety plan.

(e) The requirements of § 507.102(a)(2), (a)(4), and (a)(5) and (b) do not apply to the records required by § 507.7(e) pertaining to qualified facilities.

§ 507.102 General requirements applying to records.

(a) Records must:

(1) Be kept as original records, true copies (such as photocopies, pictures, scanned copies, microfilm, microfiche, or other accurate reproductions of the original records), or electronic records, which must be kept in accordance with part 11 of this chapter;

(2) Contain the actual values and observations obtained during monitoring;

(3) Be accurate, indelible, and legible;

(4) Be created concurrently with performance of the activity documented; and

(5) Be as detailed as necessary to provide history of work performed.

(b) All records must include:

(1) The name and location of the plant or facility;

(2) The date and time of the activity documented;

(3) The signature or initials of the person performing the activity; and

(4) Where appropriate, the identity of the product and the production code, if any.

§ 507.106 Additional requirements applying to the food safety plan.

The food safety plan must be signed and dated by the owner, operator, or agent in charge of the facility upon initial completion and upon any modification.

§ 507.108 Requirements for record retention.

(a) All records required by this part must be retained at the plant or facility for at least 2 years after the date they were prepared.

(b) Records that relate to the general adequacy of the equipment or processes being used by a facility, including the results of scientific studies and evaluations, must be retained at the facility for at least 2 years after their use is discontinued (e.g., because the facility has updated the written food safety plan (§ 507.30) or records that document validation of the written food safety plan (§ 507.45(a)).

(c) Except for the food safety plan, offsite storage of records is permitted after 6 months following the date that the record was made if such records can be retrieved and provided onsite within 24 hours of request for official review. The food safety plan must remain onsite. Electronic records are considered to be onsite if they are accessible from an onsite location.

(d) If the plant or facility is closed for a prolonged period, the records may be transferred to some other reasonably accessible location, but must be returned to the plant or facility within 24 hours for official review upon request.

PART 579—IRRADIATION IN THE PRODUCTION, PROCESSING, AND HANDLING OF ANIMAL FEED AND PET FOOD

■ 8. The authority citation for 21 CFR part 579 continues to read as follows:

Authority: 21 U.S.C. 321, 342, 343, 348, 371.

■ 9. In § 579.12, add the following sentence to the end of the paragraph to read as follows:

§ 579.12 Incorporation of regulations in part 179.

* * * Any facility that treats animal feed and pet food with ionizing radiation must comply with the requirements of part 507 of this chapter and other applicable regulations.

Note: The following appendix will not appear in the Code of Federal Regulations.

Appendix

Although the proposed rule that is the subject of this document does not include provisions for environmental monitoring or finished product testing, the Agency believes that these regimes can play a critical role in a modern food safety system. In sections XI.K and XI.L, the Agency requests comment on when and how these types of testing are an appropriate means of implementing the statutory directives set out in section 418 of the FD&C Act. In this Appendix, the Agency provides background material on these testing measures.

I. The Role of Testing as a Verification Measure in a Modern Food Safety System

A. Verification of Preventive Controls

In some respects, animal food safety is a more complex subject than human food safety in that the feeding of multiple and diverse animal species is involved, many of which are associated with human food in the form of meat, milk and eggs. However, the core principles and approaches used to assess and prevent hazards that are reasonably likely to occur in animal food are similar to those used during the manufacture of food for humans, despite differences in production practices and levels of sanitation involved (Ref. 1).

The safety of food is principally ensured by the effective implementation of scientifically valid preventive control measures throughout the food chain (Ref. 2) (Ref. 3). Prevention of hazards in animal food is much more effective than trying to differentiate safe from unsafe animal food using testing. Although testing is rarely considered a control measure, it plays a very important role in ensuring the safety of animal food. An important purpose of testing is to verify that control measures, including those related to suppliers and those verified through environmental monitoring, are controlling the hazard (Ref. 4) (Ref. 5). Testing is used in conjunction with other verification measures in the food safety system, such as audits of suppliers, observations of whether activities are being conducted according to the food safety plan, and reviewing records to determine whether process controls are meeting specified limits for parameters established in the food safety plan. Although testing may be conducted for biological, chemical, physical, or radiological hazards, the most common testing is for microbiological hazards. Thus, much of the testing described below focuses on microbial testing, but many of the issues discussed apply to testing for other hazards as well. The Agency focuses more of its discussion below on verification testing of the environment because of the increasing recognition of the benefits of such testing in identifying conditions that could result in environmental pathogens contaminating animal food; thus such verification testing is important in preventing contamination in animal food, whereas verification testing of raw materials, ingredients, and finished products is used to detect contamination that has already occurred.

As discussed in sections I.C, I.E, and I.F of this Appendix, microbial testing may include:

- Testing raw materials and ingredients to verify that suppliers have significantly minimized or prevented hazards reasonably likely to occur in the raw materials and ingredients;
- Testing the environment to verify that sanitation controls have significantly minimized or prevented the potential for environmental pathogens to contaminate animal food; and
- Testing finished product to verify that preventive controls have significantly minimized or prevented hazards reasonably likely to occur in the animal food.

Further discussion of verification of preventive controls can be found in section I.A of the Appendix of the document for the proposed rule for preventive controls for human food (78 FR 3646).

B. Scientifically Valid Sampling and Testing

Consistent with the Agency's discussion of the term ''scientifically valid'' in the proposed rule to establish CGMP requirements for dietary ingredients and dietary supplements for humans (68 FR 12158 at 12198), the Agency uses the term ''scientifically valid'' with respect to testing to mean using an approach to both sampling and testing that is based on scientific information, data, or results published in, for example, scientific journals, references, text books, or proprietary research. A scientifically valid analytical method is one that is based on scientific data or results published in, for example, scientific journals, references, text books, or proprietary research (68 FR 12158 at 12198). Sampling and testing used for verification in a food safety system must be scientifically valid if they are to provide assurance that preventive controls are effective.

C. Verification Testing of Raw Materials and Ingredients

Raw materials and ingredients are often tested as part of a supplier approval and verification program, as one of the verification activities when a preventive control that is adequate to significantly minimize or prevent the hazard is not applied at the receiving facility. The utility and frequency of raw material and ingredient testing for verification of supplier controls depend on many factors, including:

- The hazard and its association with the raw material or ingredient;
- The likelihood that the animal, or person handling the animal food, would become ill if the hazard were present in the raw material or ingredient;
- How that raw material or ingredient will be used by the receiving facility (e.g., the effect of processing on the hazard); and
- The potential for contamination of the facility's environment with the hazard in the raw material or ingredient.

Further discussion of verification testing of raw materials and ingredients can be found in section I.C of the Appendix of the document for the proposed rule for preventive controls for human food (78 FR 3646).

D. Verification of Sanitation Controls to Significantly Minimize or Prevent the Potential for an Environmental Pathogen To Contaminate Animal Food

1. Environmental Pathogens in Animal Food

Animal food can become contaminated with pathogenic microorganisms at many different steps: on the farm; in packing, manufacturing/processing, or distribution facilities; during storage or transit; at retail establishments; and at the location of the animal. Any time animal food is exposed to the environment during a manufacturing, processing, packing, or holding activity, there is the potential for the food to be contaminated with pathogenic microorganisms. As discussed in section VIII.B of the preamble, proposed § 507.3 would define the term ''environmental pathogen'' to mean a microorganism that is of animal or human health significance and is capable of surviving and persisting within the manufacturing, processing, packing, or holding environment. The environmental pathogens most frequently involved in the contamination of animal food leading to foodborne illness are *Salmonella* spp.

2. *Salmonella* spp. as an Environmental Pathogen

The Agency discusses *Salmonella* spp. in section II.E of the preamble of this document and in section I.D.2 of the Appendix of the document for the proposed rule for preventive controls for human food (78 FR 3646). *Salmonella* has been isolated from a variety of foods and it can get into food by a variety of mechanisms. The focus here is on *Salmonella* contamination from the environment, particularly as a hazard associated with low-moisture animal food such as protein meals and dry animal food (Ref. 6). In the first RFR Annual Report, 86 of the primary RFR entries reported for human and animal food were a result of *Salmonella* contaminations. Almost half of these were from low-moisture foods and 13 of these were animal food (Ref. 7).

3. Environmental Pathogens in the Plant Environment

Environmental pathogens may be introduced into a facility through raw materials or ingredients, people, or objects. Once in the facility, environmental pathogens can be a source of contamination of animal food. Further discussion of ''Environmental pathogens in the plant environment'' can be found in section I.D.4 of the Appendix of the document for the proposed rule for preventive controls for human food (78 FR 3646).

4. Contamination of Animal Food With *Salmonella* spp. From the Plant Environment

The available data and information associate insanitary conditions in animal and human food facilities with contamination of a number of foods with the environmental pathogen *Salmonella* spp. Such contamination has led to recalls and to outbreaks of foodborne illness.

In 2007, FDA identified S. Schwarzengrund, a rare serotype of *Salmonella* associated with human illness, in a pet food. The Center for Disease Control and Prevention (CDC) traced this rare strain of *Salmonella* to a pet food manufacturing facility located in Pennsylvania. Analytical tests conducted by the FDA confirmed S. Schwarzengrund at the Pennsylvania facility. A recall was issued for two brands of dry dog food and the manufacturing facility ceased operations for 5 months for cleaning and disinfecting. Despite the facility's efforts, additional S. Schwarzengrund illnesses in humans were reported to CDC. After further investigations by FDA, the pet food manufacturing facility issued a nationwide voluntary recall of all dry dog and cat food products produced at the facility over a 5 month period. This recall involved approximately 23,109 tons of dry pet foods, representing 105 brands. While no pets were reported sick, 79 people in 21 states were reported as becoming ill due to the handling of pet food contaminated with this Salmonella strain (Ref. 8).

In 2008–2009, an outbreak was linked to *Salmonella* Typhimurium in peanut butter and peanut paste (Ref. 9) (Ref. 10). This outbreak resulted in an estimated 714 illnesses, 166 hospitalizations, and 9 deaths (Ref. 10). Inspections conducted by FDA at the two implicated ingredient manufacturing facilities (which shared ingredients) revealed lack of controls to prevent product contamination from pests, from an insanitary air-circulation system, from insanitary food-contact surfaces, and from the processing environment (Ref. 11) (Ref. 12). Several strains of *Salmonella* spp. were found in multiple products and in the plant environment (Ref. 12). This outbreak led to the recall of more than 3900 animal (including pet food) and human food products containing peanut-derived ingredients (Ref. 11).

E. Role of Environmental Monitoring in Verifying the Implementation and Effectiveness of Sanitation Controls in Significantly Minimizing or Preventing the Potential for an Environmental Pathogen To Contaminate Animal Food

1. Purpose of Environmental Monitoring

The purpose of monitoring for environmental pathogens in facilities where animal food is manufactured, processed, packed, or held is to verify the implementation and effectiveness of sanitation controls intended to significantly minimize or prevent the potential for an environmental pathogen to contaminate animal food. In so doing, environmental monitoring can find sources of environmental pathogens that remain in the facility after routine cleaning and sanitizing so that the environmental pathogens can be eliminated by appropriate corrective actions (e.g., intensified cleaning and sanitizing, sometimes involving equipment disassembly). For further discussion, see section I.E. of the Appendix of the document for the proposed rule for preventive controls for human food (78 FR 3646).

2. Indicator Organisms

The term ''indicator organism'' can have different meanings, depending on the purpose of using an indicator organism. As discussed in the scientific literature, the term ''indicator organism'' means a microorganism or group of microorganisms that is indicative that (1) a food has been exposed to conditions that pose an increased risk for contamination of the food with a pathogen or (2) a food has been exposed to conditions under which a pathogen can increase in numbers (Ref. 13). This definition in the scientific literature is consistent with a definition of indicator organism established by NACMCF as one that indicates a state or condition and an index organism as one for which the concentration or frequency correlates with the concentration or frequency of another microorganism of concern (Ref. 14). FDA considers the NACMCF definition of an indicator organism to be an appropriate working definition for the purpose of this document.

Listeria spp. is an appropriate indicator organism for *L. monocytogenes.* The Agency is aware that listeriosis occurs in a number of animal species, especially ruminant animals, and is asking for comment on whether *L. monocytogenes* is an environmental pathogen of concern for animal food facilities. FDA's current thinking is that there is no currently available indicator organism for *Salmonella* spp. The Agency requests data, information, and other comment bearing on whether there is a currently available indicator organism for *Salmonella* spp. that could be used for environmental monitoring.

For additional discussion on indicator organisms, monitoring procedures, and corrective actions, see section I.E.2 through 5 of the Appendix for the proposed rule for preventive controls for human food (78 FR 3646).

F. The Role of Finished Product Testing in Verifying the Implementation and Effectiveness of Preventive Controls

Although FDA is not including a provision for finished product testing in this proposed rule, here the Agency sets out some considerations regarding the appropriate use of such testing. The utility of finished product testing for verification depends on many factors that industry currently considers in determining whether finished product testing is an appropriate approach to reducing the risk of: animals consuming contaminated food, humans handling contaminated food, and humans consuming food derived from animals that consumed contaminated food. The first such consideration is the nature of the hazard and whether there is evidence of adverse health consequences from that hazard in the animal food being produced or in a similar animal food. If the hazard were to be present in the animal food, how likely is it that illness will occur and how serious would the consequences be? The more likely and severe the illness, the greater the frequency of conducting verification testing should be. For example, *Salmonella* spp. is a hazard that could cause serious illness, particularly in children and the elderly who might get exposed to it through handling pet food products contaminated with the organism. In contrast, in situations where unlawful pesticide residues are considered reasonably likely to occur, the presence of a pesticide residue that is not approved for a specific commodity, but that is within the tolerance approved for other commodities, while deemed unsafe as a matter of law, may not actually result in illness. Thus, a firm is more likely to conduct finished product testing to verify *Salmonella* spp. control than to verify control of pesticides.

Another consideration in determining whether finished product testing is appropriate is the intended ''consumer'' of the animal food and whether indirect exposure of a susceptible population may occur. The greater the sensitivity of the intended ''consumer'' (as would be the case, for example, for dioxin contamination), the greater the likelihood that finished product testing would be used as a verification activity.

Another consideration in determining whether finished product testing is appropriate is the impact of the animal food on the contaminant. For example, depending on the animal food, pathogens may survive in the food, increase in number, or die off. Finished product testing generally is not conducted if pathogens that may be in an animal food would die off in a relatively short period of time (e.g., before the food reaches the ''consumer'').

Additional considerations in determining whether finished product testing is appropriate are the intended use of the animal food; the types of controls the supplier has implemented to minimize the potential for the hazard to be present (e.g., whether the supplier has a kill step for a pathogen); the effect of processing on the hazard; and whether a hazard can be reintroduced into a food that has been treated to significantly minimize the hazard (e.g., *Salmonella* in dry or low-moisture pet food when a flavoring is applied after heat treatment).

For an extensive discussion on finished product testing and metrics for microbiological risk management, see sections I.F and I.G of the Appendix for the proposed rule for human food (78 FR 3646).

II. The Role of Supplier Approval and Verification Programs in a Food Safety System

An animal food can become contaminated through the use of contaminated raw materials or ingredients as evident by the large recall of pet food as a result of contamination of wheat gluten with melamine (see discussion in section II.E.1of the preamble).

The development of a supplier approval and verification program is part of a preventive approach. Because many facilities acting as suppliers procure their raw materials and ingredients from other suppliers, there is often a chain of suppliers before a raw material or other ingredient reaches the manufacturer/processor. To ensure safe animal food and minimize the potential for contaminated animal food to reach the consumer, each supplier in the chain must implement preventive controls appropriate to the animal food and operation for hazards reasonably likely to occur in the raw material or other ingredient. A facility receiving raw materials or ingredients from a supplier must ensure that the supplier (or a supplier to the supplier) has implemented preventive controls to significantly minimize or prevent hazards that the receiving facility has identified as reasonably likely to occur in that raw material or other ingredient unless the receiving facility will itself control the identified hazard.

A supplier approval and verification program is a means of ensuring that raw materials and ingredients are procured from those suppliers that can meet company specifications and have appropriate programs in place, including those related to the safety of the raw materials and ingredients. A supplier approval program can ensure a methodical approach to identifying such suppliers. A supplier verification program provides initial and ongoing assurance that suppliers are complying with practices to achieve adequate control of hazards in raw materials or ingredients.

Supplier approval and verification is widely accepted in the domestic and international food safety community. The NACMCF HACCP guidelines describe Supplier Control as one of the common prerequisite programs for the safe production of food products and recommend that each facility should ensure that its suppliers have in place effective GMP and food safety programs (Ref. 14). Codex specifies that no raw material or ingredient should be accepted by an establishment if it is known to contain parasites, undesirable microorganisms, pesticides, veterinary drugs or toxic, decomposed or extraneous substances which would not be reduced to an acceptable level by normal sorting and/or processing (Ref. 15). Codex also specifies that, where appropriate, specifications for raw materials should be identified and applied and that, where necessary, laboratory tests should be made to establish fitness for use (Ref. 15).

Supplier verification activities include auditing a supplier to ensure the supplier is complying with applicable food safety requirements, such as requirements under proposed part 507. Audit activities may include a range of activities, such as on-site examinations of establishments, review of records, review of quality assurance systems, and examination or laboratory testing of product samples (Ref. 16). Other supplier verification activities include conducting testing or requiring supplier certificates of analysis (COAs), review of food safety plans and records, or combinations of activities such as audits and periodic testing.

An increasing number of establishments that sell food are independently requiring, as a condition of doing business, that their suppliers, both foreign and domestic, become certified as meeting safety (as well as other) standards. In addition, domestic and foreign suppliers (such as producers, co-manufacturers, or re-packers) are increasingly looking to third-party certification programs to assist them in meeting U.S. regulatory requirements (Ref. 16). There are many established third-party certification programs designed for various reasons that are currently being used by industry. Many third party audit schemes used to assess the industry's food safety management systems incorporate requirements for manufacturers and processors to establish supplier approval programs. An example of a food safety standard that was specifically developed for the animal food industry is Publicly Available Specification (PAS) 222:2011 (Ref. 1). This standard was developed for the animal food industry by the British Standards Institution (BSI) to specify requirements for prerequisite programs (PRPs) to assist in controlling hazards in animal food. The PAS 222:2011 requirements can be used either in conjunction with ISO 22000, food safety management systems, or as a stand-alone document.

To ensure confidence in the delivery of safe food for animals and humans worldwide, the Global Food Safety Initiative (GFSI), a benchmarking organization, was established in 2000 to drive continuous improvement in food safety management systems. Their objectives include reducing risk by delivering equivalence and convergence between effective food safety management systems and managing cost in the global food system by eliminating redundancy and improving operational efficiency (Ref. 17). GFSI has developed a guidance document as a tool that fulfills the GFSI objectives of determining equivalency between food safety management systems (Ref. 17). The document is not a food safety standard, but rather specifies a process by which food safety schemes may gain recognition, the requirements to be put in place for a food safety scheme seeking recognition by GFSI, and the key elements for production of safe food or feed, or for service provision (e.g., contract sanitation services or food transportation) in relation to food safety (Ref. 17). This benchmark document has provisions relevant to supplier approval and verification programs. For example, it specifies that a food safety standard must require that the organization control purchasing processes to ensure that all externally sourced materials and services that have an effect on food safety conform to requirements. It also specifies that a food safety standard must require that the organization establish, implement, and maintain procedures for the evaluation, approval and continued monitoring of suppliers that have an effect on food safety. Thus, all current GFSI-recognized schemes require supplier controls to ensure that the raw materials and ingredients that have an impact on food safety conform to specified requirements. The GFSI guidance document also requires audit scheme owners to have a clearly defined and documented audit frequency program, which must ensure a minimum audit frequency of one audit per year of an organization's facility (Ref. 17).

Because GFSI is a document that outlines elements of a food safety management system for benchmarking a variety of standards, it does not have details about how facilities should comply with the elements. This type of information is found in the food safety schemes that are the basis for certification programs. For example, the Safe Quality Food (SQF) 2000 Code, a HACCP-based supplier assurance code for the food industry, specifies that raw materials and services that impact on finished product safety be supplied by an Approved Supplier. SQF 2000 specifies that the responsibility and methods for selecting, evaluating, approving and monitoring an Approved Supplier be documented and implemented, and that a register of Approved Suppliers and records of inspections and audits of Approved Suppliers be maintained. SQF 2000 requires that the Approved Supplier Program contain, among other items, agreed specifications; methods for granting Approved Supplier status; methods and frequency of monitoring Approved Suppliers; and details of certificates of analysis if required.

According to SQF, the monitoring of Approved Suppliers is to be based on the prior good performance of a supplier and the risk level of the raw materials supplied. The monitoring and assessment of Approved Suppliers can include:

- The inspection of raw materials received;
- The provision of certificates of analysis;
- Third party certification of an Approved Supplier; or
- The completion of 2nd party supplier audits.

III. References

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7. FDA, "FDA Foods Program, The Reportable Food Registry: A New Approach to Targeting Inspection Resources and Identifying Patterns of Adulteration. First Annual Report: September 8, 2009–September 7, 2010," January, 2011.
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12. FDA, "Amended Form 483 (Inspectional Observations) for Peanut Corporation of America, Blakely, GA, 02/05/2009," February 2009.
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15. Codex Alimentarius Commission, "Recommended International Code of Practice General Principles of Food Hygiene, CAC/RCP 1–1969 (Rev. 4–2003)," 2003.
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17. Global Food Safety Initiative, "GFSI Guidance Document, Version 6.1." August 2011.

Dated: October 21, 2013.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2013–25126 Filed 10–25–13; 8:45 am]

BILLING CODE P

From: (b) (6)
Sent: 12/5/2019 9:30:09 AM
To: Nelson, Eric [/o=Exchange
(FYDIBOHF23SPDLT)/cn=R
Subject: Attendance at AAFCO

Good morning Eric!

Hey sorry to bother you again, but

I was trying to think of ways to stin
organization fit in the world. Food

Any thoughts you'd like to share?

[redacted]

From: Krieger, Darlene [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=E734D56D0B5B4F21A5E3D89FC0CC3917-DARLENE.KRI]
Sent: 12/2/2019 3:26:15 PM
To: Steinberg, Nadine [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cc7979a0766747eaa65ea70be87fa51e-NSteinbe]; Bair, Tonia [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=61b62fe2fb414fb2861003902258af2f-TBair]
CC: Nelson, Eric [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f90377266c0c4a68bf8ac2b4783f8ac9-ENelson]
Subject: FW: (b) (4)
Attachments: DRAFT (b) (4) Correspondence Pet Food Request for Approval (DLK)[EN].docx

Good afternoon all~
I have taken a stab at the letter and Eric has provided some comments and below is a response to Eric's comments. If you have any additional comments or edits, if you can get to me by Dec 4 at noon I can consolidate and see if I can get them addressed prior to sending to OCC. Thank you all.

Both reference are from a OCC letter to the firm. (b) (5), (b) (7)(A) I was thinking more Gophers and Vikings!!!

From: Nelson, Eric <Eric.Nelson@fda.hhs.gov>
Sent: Friday, November 29, 2019 1:41 PM
To: Krieger, Darlene <Darlene.Krieger@fda.hhs.gov>
Subject: RE: (b) (4)

Good start I had a couple of comment and edits. Go Badgers and Packers!!

Eric M Nelson
Director of Compliance
FDA/Center for Veterinary Medicine (HFV-230)
7519 Standish Place
Rockville, MD 20855-2773
office: (240) 402-5642
fax: (240) 276-9241
e-mail: Eric.Nelson@fda.hhs.gov

From: Krieger, Darlene <Darlene.Krieger@fda.hhs.gov>
Sent: Wednesday, November 27, 2019 3:55 PM
To: Nelson, Eric <Eric.Nelson@fda.hhs.gov>
Subject: RE: (b) (4)

Cant believe I forgot to attach...

From: Nelson, Eric <Eric.Nelson@fda.hhs.gov>
Sent: Wednesday, November 27, 2019 2:35 PM
To: Krieger, Darlene <Darlene.Krieger@fda.hhs.gov>
Subject: RE: (b) (4)

If you send it to me, I can review it Friday.

Eric M Nelson
Director of Compliance
FDA/Center for Veterinary Medicine (HFV-230)
7519 Standish Place
Rockville, MD 20855-2773
office: (240) 402-5642
fax: (240) 276-9241
e-mail: Eric.Nelson@fda.hhs.gov

From: Krieger, Darlene <Darlene.Krieger@fda.hhs.gov>
Sent: Wednesday, November 27, 2019 12:02 PM
To: Nelson, Eric <Eric.Nelson@fda.hhs.gov>
Subject: (b) (4)

Hey Eric,
Can you take a quick view and see if I am on the right track or if I need to add more? Thanks for the opportunity to work on this

Darlene Krieger
Consumer Safety Officer, Post-Market Compliance Animal Food Team
FDA / Center for Veterinary Medicine (CVM)
250 Marquette Ave, Suite 600
Minneapolis, MN 55401
Office Phone: (612)758-7148
Work cell: (612)308-5456

FDA U.S. FOOD & DRUG
ADMINISTRATION

UNITED PARCEL SERVICE
SIGNATURE REQUIRED

Draft November 05, 2019

(b) (4), (b) (5)

(b) (4), (b) (5)

(b) (4), (b) (5)

(b) (4), (b) (5)

(b) (4), (b) (5)

From: Turner, Tara [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=F71FC0DE503C414581E1615E0ECA3E27-TURNERT]
Sent: 12/20/2019 3:35:11 PM
To: Nanko, Nadine J [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d64109ad008b4b339e591a3fa45f229d-NNANKO]; CVM Recalls [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=16a743f46cb0489db89f355b757463a2-CVM Recalls]; Edwards, David [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=df3e3d2ae5ab4c7dabec7ecea8a82404-David.Edwar]; Hong, Michael [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7659995ebaa84f49999fbbbaf3fee034-Michael.Hon]; Kidanu, Tesfahun [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=973c12728947452b86e2d555ed4edaa0-TKIDANU]; Nelson, Eric [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f90377266c0c4a68bf8ac2b4783f8ac9-ENelson]; Vengris, Vitolis E [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=735789f6b7d14be7bdc8960c68cd7e1d-VVENGRIS]; Bataller, Neal [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2458a8e78711449395cdc90423c00a6c-NBATALLE]
CC: Atkinson, Krisztina Z [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2dc58ee5d1a84b90898f1d7862220df6-KAtkinso]
Subject: Signed HHE for The JM Smucker Company, Inc. RES 84423. This assignment has been closed in CASPER.
Attachments: HHE Completed JM Smucker RES 84423 F20072hhe_ (004).pdf

Hello,

Attached is the signed HHE for The JM Smucker Company, Inc. RES 84423. Reason for recall: (b) (4) [redacted] the products. This assignment has been closed in CASPER effective 12/20/2019.

Thank you,

Tara P. Turner, Pharm.D., MPH
CAPT, U.S. Public Health Service
Acting Recall Coordinator
Complaint Emergency Recall & Reconditioning Team (HFV-231)
Division of Compliance
FDA Center for Veterinary Medicine
301-796-2166 (office)

U.S. FOOD & DRUG
ADMINISTRATION

December 20, 2019

HEALTH HAZARD EVALUATION

Firm: The J.M. Smucker Company, Inc.
Problem: Recall of Canned Cat Food due to Excessive Choline Chloride Levels

Field Recommendation: Class I

Recall Event ID/RES #: 84423
DAF#: 20072

To: CVM Recall and Emergency Coordinator – Acting (Tara P. Turner), HFV-231

---

1. Product(s), Identification Number, Usage

Product 1: Special Kitty Mixed Grilled Dinner Pate, (b)(4) cans per case, 5.5oz cans
Codes: UPC Code (b) (4) (case), [redacted] (can)
Lot # 9263803
Quantity Distributed: (b) (4)

Product 2: Special Kitty Surf & Turf Variety Pack Pate, (b)(4) cans per case, 5.5oz cans net wt. 198oz
Codes: UPC Code 6 8113107923 5 (case), 6 8113107923 5 (can)
Lot #9266803
Quantity Distributed: (b) (4)

Product 3: Special Kitty Surf & Turf Variety Pack Pate, (b)(4) cans per case, 5.5oz cans net wt. 198oz
Codes: UPC Code 6 8113107923 5 (case), 6 8113107923 5 (can)
Lot # 9267803
Quantity Distributed: (b) (4)

Product 4: Special Kitty Surf & Turf Variety Pack Pate, 36 cans per case, 5.5oz cans net wt. 198oz
Codes: UPC Code 6 8113107923 5 (case), 6 8113107923 5 (can)
Lot # 9287803
Quantity Distributed: (b) (4)

Industry-Product Code: 72-AET02

U.S. Food and Drug Administration
Center for Veterinary Medicine
7519 Standish Place
Rockville, MD 20855
www.fda.gov

2. Firm Name, Address, Identification Number(s)

Recalling Firm: The J.M. Smucker Company, Inc.
1 Strawberry Ln.
Orrville, Ohio 44667-1241
United States
FEI 1519206

Manufacturer: (b) (4) [redacted]

Comment: On the Attachment B submitted by the recalling firm, the manufacturer's name was listed as The J.M. Smucker Company.

Recall Contact: Christopher P. Todaro
Vice President Corporate Quality
The J.M. Smucker Company, Inc.
1 Strawberry Ln.
Orrville, Ohio 44667-1241
United States
Tel.: 330-684-3230
Email: chris.todaro@smsmucker.com

(b) (4) [redacted]

(b) (4)

(b) (4)

Due to the fact that within a short time following the distribution of the product, 13 adverse events were reported about the product, we can conclude that there is a reasonable probability of adverse event occurring.

Animal Health Hazard Evaluation Committee:

Neal Bataller -S
Digitally signed by Neal Bataller -S
Date: 2019.12.20 12:02:08 -05'00'

Neal Bataller, ME, DVM, Chair date

David B. Edwards -S
Digitally signed by David B. Edwards -S
Date: 2019.12.20 11:59:47 -05'00'

David Edwards, PhD date

Linda A. Benjamin -S
Digitally signed by Linda A. Benjamin -S
Date: 2019.12.20 11:27:55 -05'00'

Linda Benjamin, PhD date

Prepared by:

Krisztina Atkinson -S
Digitally signed by Krisztina Atkinson -S
Date: 2019.12.20 11:16:36 -05'00'

Krisztina Atkinson, MS, DVM date

Tara P. Turner -S
Digitally signed by Tara P. Turner -S
DN: c=US, o=U.S. Government, ou=HHS, ou=FDA, ou=People, cn=Tara P. Turner -S, 0.9.2342.19200300.100.1.1=1300157728
Date: 2019.12.20 14:55:12 -05'00'

bcc:
HFV-210
HFV-220

File Code: VT*CH DAF#: 20072 F20072hhe_.docx

Keywords: The J.M. Smucker Company, Special Kitty Mix Grilled Dinner Pate, Special Kitty Surf & Turf Variety Pack Pate, canned cat food, (b) (4)

Final Action Code: HHE memo

Draft: Atkinson: 12/19/19
Comments: Benjamin: 12/19/19
Comments: DEdwards: 12/19/19
Comments: Vengris:12/20/19
Final: Atkinson: 12/20/19

From: Strunk, Scott [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=AFE475444CAA4670800119984A013FF3-SCOTT.STRUN]

Sent: 12/3/2019 7:45:07 AM

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Subject: CGE Trip Status Report 12/3/2019

Importance: High

Good Morning,

This is what I have currently in CGE. I have highlighted the TA Status column in GREEN if the TA has been stamped approved, YELLOW if the TA has not been approved yet and Red if the TA needs immediate attention. Any RED text indicates that something is keeping the TA from being approved.

Make sure your travelers are checking the GSA website for tax exemption forms for the tax exempt states.
This is the link to the GSA website with links to all of the tax exemption forms and information for the tax exempt states. https://smartpay.gsa.gov/content/state-tax-information

Tax exempt states- Alaska, Delaware, Florida, Kansas, Louisiana, Massachusetts, Missouri, New York, Oregon, Pennsylvania, Texas, Wisconsin, Puerto Rico, Virgin Islands				
Office	**Account Name**	**Voucher Status**	**TA Status**	**Tax Exempt**
February				
(b) (5)				

Tax exempt states- Alaska, Delaware, Florida, Kansas, Louisiana, Massachusetts, Missouri, New York, Oregon, Pennsylvania, Texas, Wisconsin, Puerto Rico, Virgin Islands				
Office	**Account Name**	**Voucher Status**	**TA Status**	**Tax Exempt**
January				
(b) (5)				

Tax exempt states- Alaska, Delaware, Florida, Kansas, Louisiana, Massachusetts, Missouri, New York, Oregon, Pennsylvania, Texas, Wisconsin, Puerto Rico, Virgin Islands				
Office	**Account Name**	**Voucher Status**	**TA Status**	**Tax Exempt**
December				
ONADE	COOK, STEPHANIE	On TDY - 12/15-19 GA - Site Visit	Approved	
ONADE	LAZO ANA	On TDY - 12/15-19 GA - Site Visit	Approved	
ONADE	HAYES, JOSHUA	On TDY - 12/14-19 Bangkok - ISAA	Approved	
ONADE	LOMBARDI, HEATHER	On TDY - 12/9-12 CA - National Academy of Sciences	Approved	
OD	EPSTEIN, LAURA	On TDY - 12/9-12 CA - National Academy of Sciences	Approved	
(b) (5)			Reviewed	
			Reviewed	
OSC	EHNEN, SANDRA	On TDY - 12/7-11 CO - AAEP	Approved	
OSC	BOWMAN, JEAN	On TDY - 12/7-11 CO - AAEP	Approved	
ONADE	RHODES, LESLIE	On TDY - 12/7-11 CO - AAEP	Approved	
ONADE	NICHOLSON, ANNE	On TDY - 12/7-11 CO - AAEP	Approved	

Thanks,
Scott Strunk

CVM/OM/PRMS
CGE Travel Administrator
CitiBank Travel Card Administrator
240-328-7354

From: Woody, Dillard [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=8E5B0815EA0046E19FDD9FFE9CA637FC-DWOODY]
Sent: 12/5/2019 8:51:08 AM
To: Gallagher, Sonia [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=bd095bb8410c4f3eb8a671d3b0df6276-SGALLAG1]; Nelson, Eric [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f90377266c0c4a68bf8ac2b4783f8ac9-ENelson]; McCoig, Amber [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=daa97064a98f4c249e0a1264311d1169-Amber.McCoi]; Castiglia, Annamaria [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f421fc3e7c4c48e68c475ce9a79eeb8a-ACastiglia]; Hodges, April [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2f96eb3112ef4669ae2aee02766538ff-April.Hodge]
Subject: RE: CGE Trip Status Report 12/5/2019

Done.

Thanks,
Woody

Dillard H. Woody Jr.
Supervisor, Post Market Drug Compliance Team
Division of Compliance
FDA/Center for Veterinary Medicine (HFV-232)
Office: 240-402-5557
e-mail: Dillard.Woody@fda.hhs.gov
internet: www.fda.gov/cvm/

From: Gallagher, Sonia <Sonia.Gallagher@fda.hhs.gov>
Sent: Thursday, December 05, 2019 8:13 AM
To: Nelson, Eric <Eric.Nelson@fda.hhs.gov>; McCoig, Amber <Amber.McCoig@fda.hhs.gov>; Woody, Dillard <Dillard.Woody@fda.hhs.gov>; Castiglia, Annamaria <AnnaMaria.Castiglia@fda.hhs.gov>; Hodges, April <April.Hodges@fda.hhs.gov>
Subject: FW: CGE Trip Status Report 12/5/2019
Importance: High

Please authorize ASAP!

(b) (5)

From: Strunk, Scott <Scott.Strunk@fda.hhs.gov>
Sent: Thursday, December 05, 2019 8:09 AM
Subject: CGE Trip Status Report 12/5/2019
Importance: High

Good Morning,

This is what I have currently in CGE. I have highlighted the TA Status column in GREEN if the TA has been stamped approved, YELLOW if the TA has not been approved yet and Red if the TA needs immediate attention. Any RED text indicates that something is keeping the TA from being approved.

Make sure your travelers are checking the GSA website for tax exemption forms for the tax exempt states.
This is the link to the GSA website with links to all of the tax exemption forms and information for the tax exempt states. https://smartpay.gsa.gov/content/state-tax-information

Tax exempt states- Alaska, Delaware, Florida, Kansas, Louisiana, Massachusetts, Missouri, New York, Oregon, Pennsylvania, Texas, Wisconsin, Puerto Rico, Virgin Islands

Office	Account Name	Voucher Status	TA Status	Tax Exempt
February				
[redacted]	[redacted]	[redacted]	[redacted]	[redacted] (b) (5)

Tax exempt states- Alaska, Delaware, Florida, Kansas, Louisiana, Massachusetts, Missouri, New York, Oregon, Pennsylvania, Texas, Wisconsin, Puerto Rico, Virgin Islands

Office	Account Name	Voucher Status	TA Status	Tax Exempt
January				
[redacted]	[redacted]	[redacted] (b) (5)	[redacted]	[redacted]

Tax exempt states- Alaska, Delaware, Florida, Kansas, Louisiana, Massachusetts, Missouri, New York, Oregon, Pennsylvania, Texas, Wisconsin, Puerto Rico, Virgin Islands

Office	Account Name	Voucher Status	TA Status	Tax Exempt
December				
ONADE	COOK, STEPHANIE	On TDY - 12/15-19 GA - Site Visit	Approved	
ONADE	LAZO ANA	On TDY - 12/15-19 GA - Site Visit	Approved	
ONADE	HAYES, JOSHUA	On TDY - 12/14-19 Bangkok - ISAA	Approved	
ONADE	LOMBARDI, HEATHER	On TDY - 12/9-12 CA - National Academy of Sciences	Approved	
OD	EPSTEIN, LAURA	On TDY - 12/9-12 CA - National Academy of Sciences	Approved	
[redacted]	[redacted]	[redacted]	[redacted]	[redacted] (b) (5)
OSC	EHNEN, SANDRA	On TDY - 12/7-11 CO - AAEP	Approved	
OSC	BOWMAN, JEAN	On TDY - 12/7-11 CO - AAEP	Approved	
ONADE	RHODES, LESLIE	On TDY - 12/7-11 CO - AAEP	Approved	
ONADE	NICHOLSON, ANNE	On TDY - 12/7-11 CO - AAEP	Approved	

Thanks,
Scott Strunk
CVM/OM/PRMS
CGE Travel Administrator

CitiBank Travel Card Administrator
240-328-7354

From: Woody, Dillard [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=8E5B0815EA0046E19FDD9FFE9CA637FC-DWOODY]
Sent: 12/12/2019 8:36:37 AM
To: Gallagher, Sonia [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=bd095bb8410c4f3eb8a671d3b0df6276-SGALLAG1]; Nelson, Eric [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f90377266c0c4a68bf8ac2b4783f8ac9-ENelson]; McCoig, Amber [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=daa97064a98f4c249e0a1264311d1169-Amber.McCoi]; Hodges, April [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2f96eb3112ef4669ae2aee02766538ff-April.Hodge]; Castiglia, Annamaria [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f421fc3e7c4c48e68c475ce9a79eeb8a-ACastiglia]; Lambkin, Sonya [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7d0c915e0dbb4948914f8552e911f30f-Sonya.Lambk]
CC: Thomas, Teresa R [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=392a29f13c704995b92f6abab52ceadd-TTHOMAS2]
Subject: RE: CGE Trip Status Report 12/12/2019

Done, thank you!

Thanks,
Woody

Dillard H. Woody Jr.
Supervisor, Post Market Drug Compliance Team
Division of Compliance
FDA/Center for Veterinary Medicine (HFV-232)
Office: 240-402-5557
e-mail: Dillard.Woody@fda.hhs.gov
internet: www.fda.gov/cvm/

From: Gallagher, Sonia <Sonia.Gallagher@fda.hhs.gov>
Sent: Thursday, December 12, 2019 8:04 AM
To: Nelson, Eric <Eric.Nelson@fda.hhs.gov>; McCoig, Amber <Amber.McCoig@fda.hhs.gov>; Woody, Dillard <Dillard.Woody@fda.hhs.gov>; Hodges, April <April.Hodges@fda.hhs.gov>; Castiglia, Annamaria <AnnaMaria.Castiglia@fda.hhs.gov>; Lambkin, Sonya <Sonya.Lambkin@fda.hhs.gov>
Cc: Thomas, Teresa R <Teresa.Thomas@fda.hhs.gov>
Subject: FW: CGE Trip Status Report 12/12/2019
Importance: High

Please authorize these TAs!

(b) (5)

Thanks, Sonia

From: Strunk, Scott <Scott.Strunk@fda.hhs.gov>
Sent: Thursday, December 12, 2019 7:57 AM
Subject: CGE Trip Status Report 12/12/2019
Importance: High

Good Morning,

This is what I have currently in CGE. I have highlighted the TA Status column in GREEN if the TA has been stamped approved, YELLOW if the TA has not been approved yet and Red if the TA needs immediate attention. Any RED text indicates that something is keeping the TA from being approved.

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This is the link to the GSA website with links to all of the tax exemption forms and information for the tax exempt states. https://smartpay.gsa.gov/content/state-tax-information

Tax exempt states- Alaska, Delaware, Florida, Kansas, Louisiana, Massachusetts, Missouri, New York, Oregon, Pennsylvania, Texas, Wisconsin, Puerto Rico, Virgin Islands

Office	Account Name	Voucher Status	TA Status	Tax Exempt
February				
				(b) (5)

Tax exempt states- Alaska, Delaware, Florida, Kansas, Louisiana, Massachusetts, Missouri, New York, Oregon, Pennsylvania, Texas, Wisconsin, Puerto Rico, Virgin Islands

Office	Account Name	Voucher Status	TA Status	Tax Exempt
January				
OSC	BARTHOLOMEW, MARY	On TDY - 1/28-30 GA - IPPE	Approved	
ONADE	PINEIRO, SILVIA	On TDY - 1/26-30 FL - Miami Winter Symposium	Authorized	YES
OSC	PILLAI, PADMAKUMAR	On TDY - 1/26-29 GA - IPPE	Approved	
OSC	TANG, LEI	On TDY - 1/26-28 GA - IPPE	Approved	
		(b) (5)		
OSC	DONNELLY, KAREN	On TDY - 1/20-23 NM - AAFCO	Approved	
				(b) (5)
OSC	SKLENKA, SARA	On TDY - 1/19-24 NM - AAFCO	Approved	
				(b) (5)
OSC	MOMCILOVIC, DRAGAN	On TDY - 1/19-23 NM - AAFCO	Approved	
OSC	EDWARDS, DAVID	On TDY - 1/18-24 NM - AAFCO	Approved	
OSC	MOSKAL, THOMAS	On TDY - 1/18-22 FL - VMX	Approved	YES
		(b) (5)		

(b) (5)				
OSC	HUEBNER, KATHERINE	On TDY - 1/10-16 CA - PAG	Approved	
Tax exempt states- Alaska, Delaware, Florida, Kansas, Louisiana, Massachusetts, Missouri, New York, Oregon, Pennsylvania, Texas, Wisconsin, Puerto Rico, Virgin Islands				
Office	**Account Name**	**Voucher Status**	**TA Status**	**Tax Exempt**
December				
(b) (5)				
ONADE	COOK, STEPHANIE	On TDY - 12/15-19 GA - Site Visit	Approved	
ONADE	LAZO ANA	On TDY - 12/15-19 GA - Site Visit	Approved	
ONADE	HAYES, JOSHUA	On TDY - 12/14-19 Bangkok - ISAA	Approved	

Thanks,
Scott Strunk
CVM/OM/PRMS
CGE Travel Administrator
CitiBank Travel Card Administrator
240-328-7354

From: Strunk, Scott [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=AFE475444CAA4670800119984A013FF3-SCOTT.STRUN]

Sent: 12/19/2019 8:02:35 AM

To: Albrecht, Aila [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d30a65fff3d748889c8e9bdf7730a686-aila.albrec]; Alewynse, Michaela G [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=352b4d9e276d45dda6adf386f1d39716-MALEWYNS]; Allen, Mary [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2a89208c0c6842958446ad07926d8c9d-MAllen1]; Andres, Charles J [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c1c09dc31e734e388d6d8aff50273fae-CANDRES]; Bailey, Julie [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=85db5db711f04aabbc63bf6318065d2f-JBailey]; Bataller, Neal [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2458a8e78711449395cdc90423c00a6c-NBATALLE]; Bensley Jr, Dennis M [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=1467f1b6509f401c8b33db79cf2b2942-DBENSLEY]; Boardman, David [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4cf3ca783fbb47359dcd564424d3f706-David.Board]; Bowman, Stephanie [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=70cd377a398048dfba9c41fd8878d58c-stephanie.b]; Bradbury, Shannon [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=533cb5ecb42c4bf5874e36ce8e5d7543-SBradbury]; Bright, Susan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5c321ed068f947d8bec439a2821f4f6e-SBright]; Burnsteel, Cindy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=07949a26da03411a91b887abb315e086-CBURNSTE]; Canter, Elizabeth [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c250e844d27743e992bc4ca922819d76-ECANTER]; Castiglia, Annamaria [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f421fc3e7c4c48e68c475ce9a79eeb8a-ACastiglia]; Chen, Edward [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=6129886f859e4c2fa9ec00e9c595e36e-ECHEN]; Clarke, Angela [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=09ecd711173a4e3db920ef6786f5bfd3-ACLARKE]; Conway, Charlotte [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=93384ceea9df43b5b8dbc7d1fb58fe67-CConway]; Desai, Urvi [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ca879570f1694ffb9a715f760cc1cbad-UDesai]; Edwards, David [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=df3e3d2ae5ab4c7dabec7ecea8a82404-David.Edwar]; Farmer, Jacqueline [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=920a029bbfc24e3d9ea9db5b509611d6-FarmerJ]; Feeney, Lauren [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b4e01e162f4446708a895d2c1ae55dd2-LFeeney]; Finnegan, Catherine M [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=07754d506e9f42929245b0290998ec1a-CFinnega]; Fleischer, Steven [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=46a23dc8f11b4244a2dfe5241bc88d84-SFLEISCH]; Fontana, Scott [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=87ed80262abc48caaff645d175fe7c34-SFontana]; Forfa, Tracey [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c0b79fc076db4f989001bd369fd3e61b-TFORFA]; Friedlander, Lynn G [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=45fc5f8240d944a6a520406af73674ce-LFRIEDLA]; Gilbert, Jeffrey M [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=80308e6a2328498abb1e3bf85e99784c-JGILBERT]; Gonzales, Raoul

[/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=19aaa3e59fc040a791ccb3e5320950b4-Raoul.Gonza]; Groesbeck, Crystal [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9b7c699402f743c3b747231cb9a1a4a4-CGroesbe]; Hartogensis, Martine [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=02df91d554d34b948fc58433d0e42073-MHARTOGE]; Hodges, April [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2f96eb3112ef4669ae2aee02766538ff-April.Hodge]; Huynh, Mai X [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b5c36a1300704ec0bf16582fcec11867-MHUYNH]; Jackson, Heidi [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=694066ca38aa4ff5b188c4b939e0708f-HJACKSON]; Jones, Jeffery [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4dbd16503f6f483aad26508fcd87864e-JJONES2]; Kerrigan, Andrea [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cea4835483d64f6f9e687bd56750e816-AKERRIGAN]; Kijak, Philip J [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dfce38fd56094a168a8840dace4572f3-PKIJAK]; Kornele, Michelle [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4d340145044443efa100975aac23888e-MKORNELE]; Lambkin, Sonya [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7d0c915e0dbb4948914f8552e911f30f-Sonya.Lambk]; Leotta, Barbara [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4e885d2bed464f71b9b1d877a6be857a-Barbara.Leo]; Lombardi, Heather [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b434743c0e7a42998bfb3321c52fa3f1-HLombardi]; Long, Charli [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8f7e70ad08e1478f894c497c6f992133-Charli.Long]; Longstaff, David G [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=3d7fc989d4b3449598216ddf3dfab85c-DLongstaff]; Lucia, Matthew [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=378bb7f6473a49649aff50384c316752-Matthew.Luc]; Luddy, Elizabeth A [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=6a898509cb5e4b1685c48e8f2619666e-ELUDDY]; Matysczak, Jennifer [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=fc25abdae46d4072858ad2a16e288aad-Jennifer.Ma]; McAdams, Dorothy R [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4d1d1501d0694e0f825cee18ca6d42ad-DMCADAMS]; McCoig, Amber [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=daa97064a98f4c249e0a1264311d1169-Amber.McCoi]; McDermott, Patrick [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=3d75459a1c2a40b8b73b8b1484c8b850-PMCDERMO]; Messenheimer, Janis R [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d959b4532a334123b9d57c2c7319daa2-JMESSENH]; Mussman, John M [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=21ca0c9f188c4c72ab27f8eb3dd0f15f-JMUSSMAN]; Nelson, Eric [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f90377266c0c4a68bf8ac2b4783f8ac9-ENelson]; O'Brien, Charles [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4889a9f34dea4b329fd80c21b52c1c28-COBRIEN]; Oeller, Margaret R [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b5e979272f444ddfa864cf7d00c47ad9-MOELLER]; Owen, Rebecca [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d233f35b08ba4ad994accf2cfbc23d35-ROwen]; Palmer, Lee Anne [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cf7c8bd53b6c45a39318a596acea7c53-LPALMER]; Popek, Michael J. [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=eb1d33bed172471ea84ac2efa569df6f-MPopek]; Reimschuessel, Renate

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Subject: CGE Trip Status Report 12/19/2019

Importance: High

Good Morning,

This is what I have currently in CGE. I have highlighted the TA Status column in GREEN if the TA has been stamped approved, YELLOW if the TA has not been approved yet and Red if the TA needs immediate attention. Any RED text indicates that something is keeping the TA from being approved.

Make sure your travelers are checking the GSA website for tax exemption forms for the tax exempt states. This is the link to the GSA website with links to all of the tax exemption forms and information for the tax exempt states. https://smartpay.gsa.gov/content/state-tax-information

Tax exempt states- Alaska, Delaware, Florida, Kansas, Louisiana, Massachusetts, Missouri, New York, Oregon, Pennsylvania, Texas, Wisconsin, Puerto Rico, Virgin Islands

Office	Account Name	Voucher Status	TA Status	Tax Exempt
February				
(b) (5)				

Tax exempt states- Alaska, Delaware, Florida, Kansas, Louisiana, Massachusetts, Missouri, New York, Oregon, Pennsylvania, Texas, Wisconsin, Puerto Rico, Virgin Islands

Office	Account Name	Voucher Status	TA Status	Tax Exempt
January				
OSC	BARTHOLOMEW, MARY	On TDY - 1/28-30 GA - IPPE	Approved	
(b) (5)				
OSC	PILLAI, PADMAKUMAR	On TDY - 1/26-29 GA - IPPE	Approved	
OSC	TANG, LEI	On TDY - 1/26-28 GA - IPPE	Approved	
(b) (5)				
(b) (5)				
OSC	MILAZZO, DIANNE	On TDY - 1/20-24 NM - AAFCO	Approved	
OSC	DONNELLY, KAREN	On TDY - 1/20-23 NM - AAFCO	Approved	
OSC	PAYNE, LLOYD	On TDY - 1/20-23 NM - AAFCO	Approved	
OSC	DAS, MANISHA	On TDY - 1/20-23 NM - AAFCO	Approved	
OSC	PALMER, LEE ANNE	On TDY - 1/20-23 NM - AAFCO	Approved	
OSC	BURKHOLDER, WILLIAM	On TDY - 1/20-23 NM - AAFCO	Approved	
OSC	CONWAY,	On TDY - 1/19-24 NM - AAFCO	Approved	

	CHARLOTTE			
OSC	SKLENKA, SARA	On TDY - 1/19-24 NM - AAFCO	Approved	
OSC	KLOMMHAUS, KEVIN	On TDY - 1/19-23 NM - AAFCO	Approved	
OSC	MOMCILOVIC, DRAGAN	On TDY - 1/19-23 NM - AAFCO	Approved	
OSC	EDWARDS, DAVID	On TDY - 1/18-24 NM - AAFCO	Approved	
OSC	MOSKAL, THOMAS	On TDY - 1/18-22 FL - VMX	Approved	YES
OSC	BOWMAN, JEAN	On TDY - 1/18-22 FL - VMX	Approved	YES
		(b) (5)		YES
				YES
OSC	BURGESS, TINA	On TDY - 1/17-22 FL - VMX	Approved	YES
			(b) (5)	YES
		(b) (5)		YES
				YES
				YES
				YES
OSC	OKELO, PHARES	On TDY - 1/12-17 MS - Inspection	Approved	
		(b) (5)		
OSC	HUEBNER, KATHERINE	On TDY - 1/10-16 CA - PAG	Approved	
		(b) (5)		
OD	FLYNN, WILLIAM	On TDY - 1/9-11 IL - AVMA	Approved	
		(b) (5)		YES

Thanks,
Scott Strunk
CVM/OM/PRMS
CGE Travel Administrator
CitiBank Travel Card Administrator
240-328-7354

From: Douglas Lueders [aafco.doug@gmail.com]
Sent: 12/12/2019 6:31:03 PM
To: Bowers, Ken [KDA] [ken.bowers@ks.gov]; Burkholder, William [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8d5fda60a4814bd290d84bd28a2a9292-BBURKHOL]; Campbell, Janet [jrcampbell@landolakes.com]; mike.davidson@cdfa.ca.gov; meghan.dicks@adm.com; Dzanis@aol.com; bob@nasda.org; dfairfield@ngfa.org; StateRFR-Ferguson, George [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4dd46592837047d8bb41b6ff84b7f9b7-George.Ferg]; jfidenzio@americanpetproducts.org; StateRFR-Geiger, Robert [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=064d353aa9654516aeb6ced2a1a92ad2-RobertGeige]; Green, Kristen M. [kristen.mary.green@uky.edu]; Emily Bulian Helmes [ebhelmes@elanco.com]; darrell.johnson@uky.edu; StateRFR-Jones, Ben [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=79f4742dab424260a61614186aa1abd9-BenJones]; Douglas Lueders [AAFCO.DOUG@gmail.com]; Nelson, Eric [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f90377266c0c4a68bf8ac2b4783f8ac9-ENelson]; StateRFR-Teneyck, Richard [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ed6fce9a806d4043bb1b53f98b2f1915-RichardTene]; Angele Thompson [tpettec@gmail.com]; Pat@petfoodinstitute.org; syounker@milkspecialties.com; Ziehr - CDA, Scott [scott.ziehr@state.co.us]; StateRFR-Therrell, Austin [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2a33cb63b8ec49ad984af69c85ffc3c3-Austin.Ther]; Jennifer Roland [JenniferR@assochq.org]
Subject: Re: DRAFT Albuquerque MBRC agenda
Attachments: Proposed Revision to PF7 & Feeding Protocols Corrected 8-29-2019[kv1739830-1739831] (1) (1).docx

Good afternoon all,
I have a correction to attachment F in yesterday's email Please substitute This Attachment F for the one sent yesterday.

Regards,
Doug Lueders
AAFCO MBRC Chair
651-448-1100

On Mon, Nov 11, 2019 at 3:14 PM Douglas Lueders <aafco.doug@gmail.com> wrote:

> Good afternoon all.
> Please see the attached Draft Agenda for the MBRC Meeting in Albuquerque. It is a a relatively light agenda. As always I'm open for additional suggestions. Please review your daily feed (animal food) work and see if there are issues that could use MBRC input and let me know.
>
> Regards,
> Doug Lueders
> AAFCO MBRC Chair
> 651-448-1100

AAFCO
Association of American Feed Control Officials

Proposed Revision to PF7 & Feeding Protocols (ATTACHMENT F)

Pet Food Committee Recommendation:

The PFC recommends that the following revisions be considered by the MBRC for integration into the AAFCO Official Publication.

Background

Revising requirements to the Feeding Protocols to account for the special nutritional requirements for growth of large size dogs. DRAFT language.

> **Note:** Revised for correct formatting, clarity and plain language, and to include wording to be placed in the Protocols Section of the OP.

Workgroup Recommendations:

Regulation PF7. Nutritional Adequacy

(a) The label of a pet food or specialty pet food which is intended for all life stages and sizes of the pet or specialty pet may include an unqualified claim, directly or indirectly, such as "complete and balanced," "perfect," "scientific," or "100% nutritious" if at least one of the following apply:

- (1) The product meets the nutrient requirements for all life stages and sizes established by an AAFCO-recognized nutrient profile; or
- (2) The product meets the criteria for all life stages as substantiated by completion of the appropriate AAFCO-recognized animal feeding protocol(s);
  - A. Unqualified claims of nutritional adequacy that include large size dogs can be substantiated by completing the appropriate protocols using large size dogs; or
  - B. Can be substantiated by completing the appropriate protocols using dogs less than 70 lbs. adult weight while containing no more calcium and phosphorus than the maximum limits for large size dogs listed in the AAFCO Dog Food Nutrient Profiles; or
- (3) The product is a member of a product family which is nutritionally similar to a lead product which contains a combination of ingredients

that has been fed to a normal animal as the sole source of nourishment in accordance with the testing procedures established by AAFCO for all life stages, provided that:

A. The nutritional similarity of the family product can be substantiated according to the Procedures for Establishing Pet Food Product Families developed by AAFCO; and

B. The family product meets the criteria for all life stages; and

C. Under circumstances of reasonable doubt, the (State Control Official) may require the manufacturer to perform additional testing of the family product in order to substantiate the claim of nutritional adequacy.

(b) The label of a pet food or specialty pet food which is intended for a limited purpose (such as size of dog) or a specific life stage, but not for all life stages and sizes, may include a qualified claim such as "complete and balanced," "perfect," "scientific," or "100% nutritious" when the product and claim meet all of the following:

(1) The claim is qualified with a statement of the limited purpose or specific life stage for which the product is intended or suitable, for example, "complete and balanced for puppies (or kittens)." The claim and the required qualification shall be juxtaposed on the same label panel and in the same size, style and color print; and

(2) The product meets at least one of the following:

A. The nutrient requirements for the limited purpose or specific life stage established by an AAFCO-recognized nutrient profile; or

B. The criteria for a limited purpose or a specific life stage as substantiated by completion of the appropriate AAFCO-recognized animal feeding protocol(s);

i. Qualified claims of nutritional adequacy that include large size dogs can be substantiated by completing the appropriate protocols using large size dogs; or

ii. Can be substantiated by completing the appropriate protocols using dogs less than 70 lbs. adult weight while containing no more calcium and phosphorus than the maximum limits for large size dogs listed in the AAFCO Dog Food Nutrient Profiles; or

C. The requirements of a product family which is nutritionally similar to a lead product which contains a combination of ingredients which, when fed for such limited purpose, will satisfy the nutrient requirements for such limited purpose and has had its capabilities in this regard demonstrated by adequate testing, and provided that:

i. The nutritional similarity of the family product can be substantiated according to the Procedures for Establishing Pet Food Product Families developed by

    AAFCO; and
  ii. The family product meets the criteria for such limited purpose; and
  iii. Under circumstances of reasonable doubt, the (State Control Official) may require the manufacturer to perform additional testing for the family product to substantiate the claim of nutritional adequacy.

(c) Dog and cat food labels shall include a statement of nutritional adequacy or purpose of the product except when the dog or cat food is clearly and ….

Language for Insertion into the Feeding Protocols (in red)

AAFCO Dog and Cat Food Nutrient Profiles—Introduction

The Pet Food committee recommends that the revisions to the AAFCO Dog and Cat Food Nutrient Profiles not be enforced until 12 months (1/1/2017) for new products in development and 24 months (1/1/2018) for existing products after publication of the revised AAFCO Dog and Cat Food Nutrient Profiles in the print version of the AAFCO OP.

[…]

The established profiles are the "AAFCO Dog Food Nutrient Profiles" and "AAFCO Cat Food Nutrient Profiles" as the terms are applied in AAFCO model pet food regulations referring to nutritional adequacy. Under these model regulations, dog and cat foods substantiated for nutritional adequacy by reference to the AAFCO Dog and Cat Food Nutrient Profiles for a designated life stage(s) must be formulated to contain at least the minimum concentrations of nutrients specified in the Profiles, and, for some nutrients, not more than any maximum concentration listed for that specific nutrient in the Profiles as shown in this section. Products with their nutritional adequacy substantiated by AAFCO Feeding Protocols are not mandated to meet the minimum or maximum concentrations listed in the Profiles, except for large-size dogs growth and all life stage products substantiated by the protocols using non-large size dogs must contain no more than the maximum large size breed calcium and phosphorus concentrations listed in the profiles. Additionally, snacks, treats or products intended for intermittent or supplemental feeding only are not mandated to meet the concentrations in the Profiles unless their labeling references the Profiles.

[…]

MINIMUM FEEDING PROTOCOL FOR PROVING AN UNQUALIFIED REPRESENTATION OF NUTRITIONAL ADEQUACY FOR A DOG OR CAT FOOD

The minimum testing necessary to prove an unqualified claim for nutritional adequacy may be obtained by using the gestation/lactation and the growth protocols.

[…]

Test puppies or kittens shall receive the test diet as their sole source of nourishment, other than dam's or queen's milk, during lactation, weaning, and growth.

Selection of puppies or kittens shall be on a statistically sound basis from each of the litters qualifying for the gestation/lactation protocol with equal sex distribution preferred.

Unqualified claims of nutritional adequacy for a product to be fed to large size dogs can be substantiated by completing the gestation/lactation and the growth protocols using large size dogs or can be substantiated by completing the gestation/lactation and the growth protocols with dogs less than 70 lbs. adult weight in which the product contains no more calcium and phosphorus than the maximum limits for large size dogs listed in the AAFCO Dog Food Nutrient Profiles.

[…]

MINIMUM FEEDING PROTOCOL FOR PROVING A GROWTH CLAIM FOR A DOG FOOD

PUPPIES

A minimum of eight puppies from three different bitches shall be required to start the test.

[…]

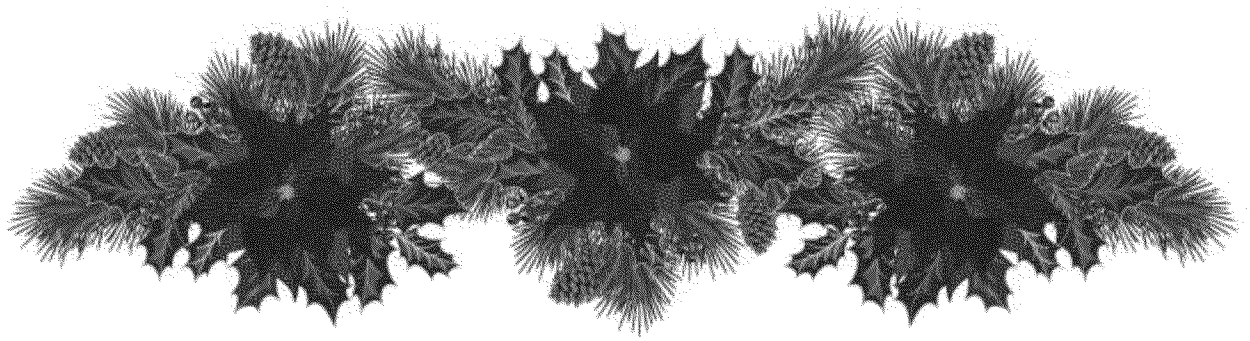
The test group shall have the same gender distribution as the concurrent control group.

A growth claim of nutritional adequacy for a product that includes large size dogs can be substantiated by completing the growth protocol using large size dogs or can be substantiated by completing the growth protocol using dogs less than 70 lbs. adult weight in which the product contains no more calcium and phosphorus than the maximum limits for large size dogs listed in the AAFCO Dog Food Nutrient Profiles.

[…]

From: AAFCO [noreply@assochq.org]
Sent: 12/18/2019 3:10:37 PM
To: Nelson, Eric [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f90377266c0c4a68bf8ac2b4783f8ac9-ENelson]
Subject: End of Year Message from AAFCO President Bob Geiger

AAFCO
Association of American Feed Control Officials



To our AAFCO family,

As we approach the end of 2019 and look forward to the upcoming holidays, I wanted to take a moment to share a few thoughts with you. First and foremost, thank you for allowing me to serve as your president this year. This has been a challenging year, but we have also accomplished many new positive things. I have been fortunate to have a great, hard-working board of directors providing many hours of work and great ideas. It truly has been a highlight of my career to serve as your president.

I want to let you know that Jennifer Roland has left FASS and is now working with NASDA. Jennifer has been a tremendous asset and friend. Please join me in wishing her and her family the best in her new endeavors!

We all come from varied backgrounds, traditions, and nations. As we gather with family and friends this holiday season, let our hearts embrace the most important things life has to offer. Take some time to reflect on the positives of life and how many blessings we have. I hope you give and receive the following three gifts this year.

The first gift is forgiveness. We all have regrets in our lives and tend to hang onto things more than we should. We can let go and lighten our burden by forgetting but may still have that nagging feeling. Darkness cannot drive out darkness; only light can do that. True forgiveness is the only way to eliminate the hindrance. May forgiveness be a gift to yourself. I hope you find forgiveness in your heart and forgiveness from others.

The second gift is joy. Joy multiplies when it is shared among friends. The sparkle and twinkle in the eyes and smiles of children are truly gifts of joy. The root of joy is gratefulness. It is not joy that makes us grateful; it is gratitude that makes us joyful. Take time to think about the blessings and friendships each of us have and share the joy with each other.

The third gift is hope. Often, things look bleak and hardships are encountered. Hope is the promise of a new tomorrow. Often we cannot see the forest for the trees. There is strange comfort in knowing that no matter what happens today, the sun will rise again tomorrow. May you find the strength and faith to endure.

In closing, I leave you with one of my favorite quotes: “And that’s what Christmas is all about, Charlie Brown!” —Linus van Pelt

Thank you again, and happy holidays.

Bob

Association of American Feed Control Officials (AAFCO)
1800 S Oak St Ste 100
Champaign, IL 61820-6974
Phone: (217) 356-4221
Email: aafco@aafco.org

Unsubscribe

From: Milazzo, Dianne H. [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=B86C7EDC7F1F4DC793D3E9050E03C633-DMILAZZO]
Sent: 12/18/2019 4:23:30 PM
To: Dutcher, Michael [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9a4834bd8f234447a79607baef948cbf-Michael.Dut]; Givens, Joann [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d4662a85c18341daa995f76ccf1f4169-JGIVENS]; Howard King, Vinetta [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=483818dd7b704eb1b886a4140c892063-VKing]; Nelson, Eric [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f90377266c0c4a68bf8ac2b4783f8ac9-ENelson]; Murphy, Jeanette [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=33924473c58f48519da2ce0c7f8ba851-JMURPHY]; Danielson, Dan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cfea06ebfb28455195494692f7f63bf8-Dan.Daniels]; Weigner, Timothy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c850e5a7ac89413bbf524d6766f64d21-Timothy.Wei]; Walker, Brenita [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2c4feafb15534c68a72773091795b7ba-Brenita.Wal]
Subject: RE: Jennifer Roland

She has accepted a job with NASDA so you will see her at the January Pilot in San Antonio, TX, if you are attending.

Dianne H. Milazzo, Consumer Safety Officer
Office of Surveillance & Compliance
FDA/ Center for Veterinary Medicine (HFV-200)
BB: 804-334-4350
VOIP: 240-402-6670
dianne.milazzo@fda.hhs.gov

From: Dutcher, Michael <Michael.Dutcher@fda.hhs.gov>
Sent: Wednesday, December 18, 2019 3:22 PM
To: Givens, Joann <Joann.Givens@fda.hhs.gov>; Howard King, Vinetta <Vinetta.HowardKing@fda.hhs.gov>; Nelson, Eric <Eric.Nelson@fda.hhs.gov>; Murphy, Jeanette <Jenny.Murphy@fda.hhs.gov>; Danielson, Dan <Dan.Danielson@fda.hhs.gov>; Weigner, Timothy <Timothy.Weigner@fda.hhs.gov>; Walker, Brenita <Brenita.Walker@fda.hhs.gov>; Milazzo, Dianne H. <Dianne.Milazzo@fda.hhs.gov>
Subject: FYI: Jennifer Roland

FYI.

I saw the announcement that Jennifer was leaving AAFCO and had no idea where she was going.

Maybe y'all already knew this, but I didn't. Thought I'd share just in case!

Now I know! 😆

Mick

Michael Dutcher, DVM
District Director
Minneapolis District
Office of Human and Animal Foods - Division I West (MN, ND, SD and WI)
U.S. Food and Drug Administration

250 Marquette Avenue, Suite 600, Minneapolis, MN 55401
office: 612.758.7124 **| mobile:** 612.616.6437 | **fax:** 612.334.4134
email: michael.dutcher@fda.hhs.gov

From: Jennifer Roland <jennifer.roland@nasda.org>
Sent: Wednesday, December 18, 2019 1:57 PM
To: Dutcher, Michael <Michael.Dutcher@fda.hhs.gov>
Subject: RE: NASDA meeting in Albuquerque January 24-25

Mick

My last day at FASS/AAFCO was December 6th. I started at NASDA on December 9th. I didn't go far I am actually working remotely from my home in Illinois for NASDA. You will still get to see me at meetings just in a different capacity now I will be representing NASDA. I am excited for this new opportunity and looking forward to still getting to work with all my AAFCO people!

I hope you have a Merry Christmas and I will see you in San Antonio 😊

Jennifer Roland | Coordinator, Food Safety Programs | **National Association of State Departments of Agriculture** | 4350 North Fairfax Drive Suite 910 Arlington, VA 22203 | (571) 447 -5321 | jennifer.roland@nasda.org

From: Ziehr - CDA, Scott [scott.ziehr@state.co.us]
Sent: 12/20/2019 3:45:05 PM
To: Conway, Charlotte [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=93384ceea9df43b5b8dbc7d1fb58fe67-CConway]; Lambkin, Sonya [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7d0c915e0dbb4948914f8552e911f30f-Sonya.Lambk]; Nelson, Eric [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f90377266c0c4a68bf8ac2b4783f8ac9-ENelson]; Edwards, David [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=df3e3d2ae5ab4c7dabec7ecea8a82404-David.Edwar]
CC: Hollis Glenn - CDA [hollis.glenn@state.co.us]
Subject: 2020 AAFCO Seminar

Greetings,

We are in the planning stages for the 2020 AAFCO Feed Administrator Seminar to be held May 5-7, 2020 in Estes Park, CO. Current topics for this seminar include African Swine Fever, laboratory-program relations, Regulatory Program Standards Coordinator Manual, as well as other topics.

We would like to extend an invitation to the FDA to attend this meeting. We still have a few time slots open on the agenda for FDA topics. Our members have expressed an interest in hearing the FDA perspective on regulatory discretion, particularly in regards to hemp, cbd, and other unapproved additives both in feed and in supplements.

Please let me know of your interest in attending as well as any topics you might want to present.

Thank you,

Scott Ziehr, MSc
Regulatory Administrator
Technical Services Section

P 303.869.9097
305 Interlocken Parkway, Broomfield, CO 80021
scott.ziehr@state.co.us | www.colorado.gov/ag

From: AAFCO [dontreply@assochq.org]
Sent: 12/2/2019 1:29:05 PM
To: Nelson, Eric [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f90377266c0c4a68bf8ac2b4783f8ac9-ENelson]
Subject: [Webinar] Steps to establish a new pet food ingredient

AAFCO
Association of American Feed Control Officials

New pet food ingredients: follow these steps to legally use

Great news! This special webinar is coming next week on Tuesday, December 3, at 9 a.m. Central Time. Join your colleagues as AAFCO Executive Director Susan M. Hays presents the process to establish a new pet food ingredient for products sold in the United States Reserve your space now for easy access to the presentation.

Get it on demand:

If you can't participate on December 3, register to receive on-demand access. Then you can watch on your preferred device anywhere.

Pass this email along to your colleagues and invite them to attend.

What you will learn:

- Develop an understanding of the AAFCO Ingredient Definitions process.
- Discover what resources exist for the requester.
- Understand the contents of a complete definition request package.
- Identify the timelines and steps in the AAFCO process.

Speaker:

Susan M. Hays
Executive Director, AAFCO

Tuesday, December 3, at
9 a.m. CST (Chicago) /
3 p.m. GMT (London) /
11 p.m. CST (Beijing)

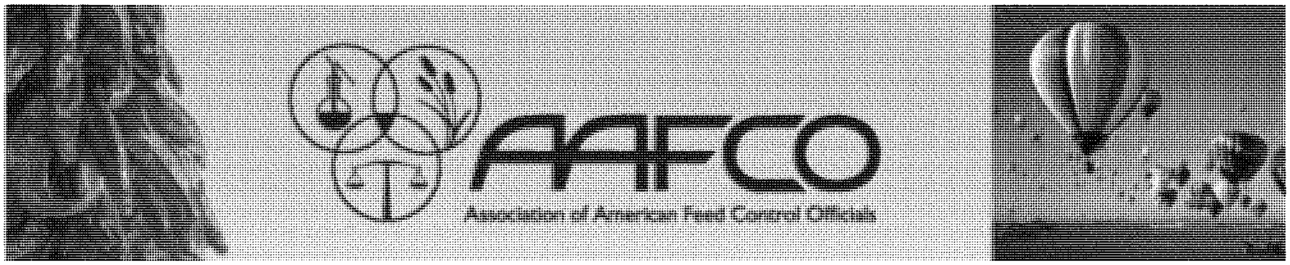
REGISTER NOW

Association of American Feed Control Officials (AAFCO)
1800 S Oak St Ste 100
Champaign, IL 61820-6974
Phone: (217) 356-4221
Email: aafco@aafco.org

Unsubscribe

From: AAFCO [noreply@assochq.org]
Sent: 12/16/2019 2:20:09 PM
To: Nelson, Eric [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f90377266c0c4a68bf8ac2b4783f8ac9-ENelson]
Subject: AAFCO Midyear early registration ends Friday, December 20. You'll want to get the discount!

AAFCO 2020 Midyear Meeting



January 21–23, 2020 • Albuquerque, New Mexico

Did you register yet?

Hurry! Early registration ends Friday, December 20. You'll want to get the discount!

Hotel room block expires December 20, 2019.

Suggested Travel Schedules:

Medicated Feed Labeling Workshop, Monday, January 20
Arrive in Albuquerque: Sunday, January 19
One-day session: Monday, January 20, 8:00 a.m. to 5:00 p.m.
Details of the day's schedule are below in this email.

Midyear Meeting Only
Arrive in Albuquerque: Monday, January 20
Sessions begin Tuesday, January 21, at 8:00 a.m. and continue Wednesday, January 22, at 8:00 a.m.
Meet and Greet Reception: Wednesday evening, January 22
Sessions end: Thursday, January 23, at noon

Dear Eric Nelson,

On behalf of the Association of American Feed Control Officials (AAFCO), I invite you to attend the AAFCO 2020 Midyear Meeting from January 21 to 23 at the Hyatt Regency Albuquerque, 330 Tijeras Ave. NW, in downtown Albuquerque, New Mexico.

You can make this meeting meaningful and productive when you take advantage of opportunities for

- one-on-one conversations,
- valuable group discussions on topics that affect your business, and

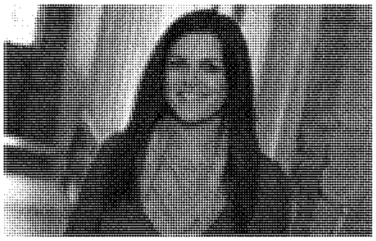
- networking with control officials, industry representatives, and others working together on animal feed and pet food issues.

Registration and hotel information is available on our website.

First-Time Registrant? Returning Registrant? Here is How to Register:

- *Online, Pay by Credit/Debit Card:* Using a secure login you set up (use for any future online AAFCO transactions, such as your *Official Publication* purchase), submit your registration and payment through our website portal.
- *Pay by Check:* Download the PDF registration form, fill it in, and either
  - fax it to 217-398-4119 or
  - send a scan to aafco@aafco.org, to the attention of Cara Tharp.

General Session Keynote Speaker!



Food Systems Security: Feeding the World

Michelle Miller, better known as the Farm Babe, is an online influencer, columnist for AGDAILY.com, international keynote speaker, and farmer. She is based in northeast Iowa with her boyfriend, where they raise sheep and beef cattle and grow 2,000 acres of corn, soybeans, oats, hay, and rye. Miller will be speaking on Food Systems Security: Feeding the World.

Workshop for 2020 Midyear Meeting

Reserve your seat now for the one-day **Medicated Feed Labeling Workshop** on Monday, January 20, from 8:00 a.m. to 5:00 p.m. The registration fee for the workshop ($125 for members and $250 for nonmembers) is in addition to the AAFCO Midyear Meeting registration fee and includes a continental breakfast and morning and afternoon breaks (lunch on your own).

This Medicated Feed Labeling Workshop is designed to empower control officials, individuals from the feed industry, drug sponsors, and others with a better understanding of medicated feed labeling, its origins, its significance, and the regulatory framework. This one-day workshop will cover the basics of medicated feed labeling as well as complex issues related to the Veterinary Feed Directive and other relevant topics. A good understanding of medicated feed labeling is essential for safe and effective use of new animal drugs in animal feed and for compliance with regulations.

Speakers include

- Dragan Momcilovic—FDA, Center for Veterinary Medicine
- Melissa Glenn—FDA, Center for Veterinary Medicine Division of Production Drugs
- Dr. Mike Apley—Kansas State University

This workshop was last offered in 2016, so if you need help with medicated feed labeling, this is your chance to learn from the experts. Don't let this chance pass you by!

Need to order your 2020 *Official Publication* (OP)? Click here to order now!

Not Sure the OP is a Good Tool for You?

Each registrant without current OP access will receive a free two-week trial of the 2020 online OP, the Online Database of Ingredients (ODI), and the AAFCO Feed BIN if you select this option while registering. When you decide to purchase the full OP subscription at the conclusion of the two-week trial, your ODI lists will transfer to your full-year subscription.

The Feed BIN: AAFCO's Communication Platform
The BIN brings you access to AAFCO reference documents, news, calendar events, committee information, team communications, and much more! The online OP is accessed through the BIN, as is the ODI. This is where AAFCO assembles information for members and industry—it is our library!

A Note About Albuquerque
Known for the work of artisans from the surrounding area, Albuquerque offers distinctive pottery, hand-crafted silver jewelry and decorative items, and other art. No matter your interests, the city has countless opportunities for you to explore, from its history dating back to the Spanish conquistadors to its diverse cultures to its authentic art. Check out things to do.

Hotel reservations **must be made by December 20.**

Early registration for the meeting ends on **December 20**. If you have any questions, please contact Cara Tharp by telephone at 217-356-4221 or by email at aafco@aafco.org.

I look forward to seeing you soon in Albuquerque!

Sincerely,
Bob Geiger
2019 AAFCO President
Office of the Indiana State Chemist
president@aafco.org

AAFCO.org/Meetings/Midyear/2020

AAFCO Headquarters Office
1800 S Oak St Ste 100 • Champaign, IL 61820-6974
Phone: 217.356.4221 • Fax: 217.398.4119
Email: aafco@aafco.org
Unsubscribe

From: Klommhaus, Kevin [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=CD18A1B1527044B0BB0248E889E73E11-KEVIN.KLOMM]
Sent: 12/9/2019 9:33:29 AM
To: Williams, Susan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=63c605573234410491fad54cde597ecd-Susan.Willi]; Steinberg, Nadine [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cc7979a0766747eaa65ea70be87fa51e-NSteinbe]; Nelson, Eric [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f90377266c0c4a68bf8ac2b4783f8ac9-ENelson]; Bair, Tonia [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=61b62fe2fb414fb2861003902258af2f-TBair]; Lambkin, Sonya [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7d0c915e0dbb4948914f8552e911f30f-Sonya.Lambk]; Cash, Elizabeth [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e79e7b9b159746428e1d766fc34e447f-Elizabeth.C]
Subject: RE: Lystn v. FDA; For review by Friday morning - FDA opposition to Lystn's motion to amend the complaint

I have them filed, and will be placing the documents into Sharepoint as well.

Sincerely

Kevin E. Klommhaus

From: Williams, Susan <Susan.Williams@fda.hhs.gov>
Sent: Friday, December 6, 2019 6:12 PM
To: Steinberg, Nadine <Nadine.Steinberg@fda.hhs.gov>; Nelson, Eric <Eric.Nelson@fda.hhs.gov>; Bair, Tonia <Tonia.Bair@fda.hhs.gov>; Lambkin, Sonya <Sonya.Lambkin@fda.hhs.gov>; Klommhaus, Kevin <Kevin.Klommhaus@fda.hhs.gov>; Cash, Elizabeth <Elizabeth.Cash@fda.hhs.gov>
Subject: RE: Lystn v. FDA; For review by Friday morning - FDA opposition to Lystn's motion to amend the complaint

For your files – FDA's and AAFCO's responses to Lystn's motion to amend the complaint with its FACA claim. (b) (5) [redacted]

From: Williams, Susan
Sent: Tuesday, December 03, 2019 6:23 PM
To: Steinberg, Nadine <Nadine.Steinberg@fda.hhs.gov>; Nelson, Eric <Eric.Nelson@fda.hhs.gov>; Bair, Tonia <Tonia.Bair@fda.hhs.gov>; Lambkin, Sonya <Sonya.Lambkin@fda.hhs.gov>; Klommhaus, Kevin <Kevin.Klommhaus@fda.hhs.gov>; Cash, Elizabeth <Elizabeth.Cash@fda.hhs.gov>
Subject: Lystn v. FDA; For review by Friday morning - FDA opposition to Lystn's motion to amend the complaint

Attached for your review is FDA's opposition to Lystn's motion to amend its complaint to include the FACA claim based on AAFCO allegedly being an FDA advisory committee.

Please return comments to me by 10 am Friday, 12/6 – it is due in court by the end of that day. Thanks!

Susan

From: Williams, Susan [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=63C605573234410491FAD54CDE597ECD-SUSAN.WILLI]
Sent: 12/3/2019 6:23:23 PM
To: Steinberg, Nadine [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cc7979a0766747eaa65ea70be87fa51e-NSteinbe]; Nelson, Eric [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f90377266c0c4a68bf8ac2b4783f8ac9-ENelson]; Bair, Tonia [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=61b62fe2fb414fb2861003902258af2f-TBair]; Lambkin, Sonya [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7d0c915e0dbb4948914f8552e911f30f-Sonya.Lambk]; Klommhaus, Kevin [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd18a1b1527044b0bb0248e889e73e11-Kevin.Klomm]; Cash, Elizabeth [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e79e7b9b159746428e1d766fc34e447f-Elizabeth.C]
Subject: Lystn v. FDA; For review by Friday morning - FDA opposition to Lystn's motion to amend the complaint
Attachments: Lystn.20191206.OppositionToMotionToAmendDRAFT.docx

Attached for your review is FDA's opposition to Lystn's motion to amend its complaint to include the FACA claim based on AAFCO allegedly being an FDA advisory committee.

Please return comments to me by 10 am Friday, 12/6 – it is due in court by the end of that day. Thanks!

Susan

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From: Bair, Tonia [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=61B62FE2FB414FB2861003902258AF2F-TBAIR]
Sent: 12/4/2019 5:16:41 PM
To: Williams, Susan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=63c605573234410491fad54cde597ecd-Susan.Willi]; Steinberg, Nadine [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cc7979a0766747eaa65ea70be87fa51e-NSteinbe]; Nelson, Eric [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f90377266c0c4a68bf8ac2b4783f8ac9-ENelson]; Lambkin, Sonya [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7d0c915e0dbb4948914f8552e911f30f-Sonya.Lambk]; Klommhaus, Kevin [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd18a1b1527044b0bb0248e889e73e11-Kevin.Klomm]; Cash, Elizabeth [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e79e7b9b159746428e1d766fc34e447f-Elizabeth.C]
Subject: RE: Lystn v. FDA; For review by Friday morning - FDA opposition to Lystn's motion to amend the complaint
Attachments: Lystn.20191206.OppositionToMotionToAmendDRAFT(TB review).docx

I had just two very minor (and non-substantive) comments.

From: Williams, Susan <Susan.Williams@fda.hhs.gov>
Sent: Wednesday, December 04, 2019 4:02 PM
To: Steinberg, Nadine <Nadine.Steinberg@fda.hhs.gov>; Nelson, Eric <Eric.Nelson@fda.hhs.gov>; Bair, Tonia <Tonia.Bair@fda.hhs.gov>; Lambkin, Sonya <Sonya.Lambkin@fda.hhs.gov>; Klommhaus, Kevin <Kevin.Klommhaus@fda.hhs.gov>; Cash, Elizabeth <Elizabeth.Cash@fda.hhs.gov>
Subject: RE: Lystn v. FDA; For review by Friday morning - FDA opposition to Lystn's motion to amend the complaint

Thanks, Nadine

From: Steinberg, Nadine <Nadine.Steinberg@fda.hhs.gov>
Sent: Wednesday, December 04, 2019 3:59 PM
To: Williams, Susan <Susan.Williams@fda.hhs.gov>; Nelson, Eric <Eric.Nelson@fda.hhs.gov>; Bair, Tonia <Tonia.Bair@fda.hhs.gov>; Lambkin, Sonya <Sonya.Lambkin@fda.hhs.gov>; Klommhaus, Kevin <Kevin.Klommhaus@fda.hhs.gov>; Cash, Elizabeth <Elizabeth.Cash@fda.hhs.gov>
Subject: RE: Lystn v. FDA; For review by Friday morning - FDA opposition to Lystn's motion to amend the complaint

Hi Susan,
I've reviewed and have no comments. Thanks,
Nadine

From: Williams, Susan <Susan.Williams@fda.hhs.gov>
Sent: Tuesday, December 03, 2019 6:23 PM
To: Steinberg, Nadine <Nadine.Steinberg@fda.hhs.gov>; Nelson, Eric <Eric.Nelson@fda.hhs.gov>; Bair, Tonia <Tonia.Bair@fda.hhs.gov>; Lambkin, Sonya <Sonya.Lambkin@fda.hhs.gov>; Klommhaus, Kevin <Kevin.Klommhaus@fda.hhs.gov>; Cash, Elizabeth <Elizabeth.Cash@fda.hhs.gov>
Subject: Lystn v. FDA; For review by Friday morning - FDA opposition to Lystn's motion to amend the complaint

Attached for your review is FDA's opposition to Lystn's motion to amend its complaint to include the FACA claim based on AAFCO allegedly being an FDA advisory committee.

Please return comments to me by 10 am Friday, 12/6 – it is due in court by the end of that day. Thanks!

Susan

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From: Williams, Susan [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=63C605573234410491FAD54CDE597ECD-SUSAN.WILLI]
Sent: 12/6/2019 7:12:13 PM
To: Steinberg, Nadine [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cc7979a0766747eaa65ea70be87fa51e-NSteinbe]; Nelson, Eric [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f90377266c0c4a68bf8ac2b4783f8ac9-ENelson]; Bair, Tonia [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=61b62fe2fb414fb2861003902258af2f-TBair]; Lambkin, Sonya [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7d0c915e0dbb4948914f8552e911f30f-Sonya.Lambk]; Klommhaus, Kevin [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd18a1b1527044b0bb0248e889e73e11-Kevin.Klomm]; Cash, Elizabeth [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e79e7b9b159746428e1d766fc34e447f-Elizabeth.C]
Subject: RE: Lystn v. FDA; For review by Friday morning - FDA opposition to Lystn's motion to amend the complaint
Attachments: FDA opposition to motion to amend.pdf; AAFCO opposition motion to amend.pdf

For your files – FDA's and AAFCO's responses to Lystn's motion to amend the complaint with its FACA claim. (b) (5)

From: Williams, Susan
Sent: Tuesday, December 03, 2019 6:23 PM
To: Steinberg, Nadine <Nadine.Steinberg@fda.hhs.gov>; Nelson, Eric <Eric.Nelson@fda.hhs.gov>; Bair, Tonia <Tonia.Bair@fda.hhs.gov>; Lambkin, Sonya <Sonya.Lambkin@fda.hhs.gov>; Klommhaus, Kevin <Kevin.Klommhaus@fda.hhs.gov>; Cash, Elizabeth <Elizabeth.Cash@fda.hhs.gov>
Subject: Lystn v. FDA; For review by Friday morning - FDA opposition to Lystn's motion to amend the complaint

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Please return comments to me by 10 am Friday, 12/6 – it is due in court by the end of that day. Thanks!

Susan

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLORADO

Civil Action No. 19-cv-01943-PAB-KLM

LYSTN, LLC, d/b/a ANSWERS™ PET FOOD,

Plaintiff,

v.

FOOD AND DRUG ADMINISTRATION, et al.,

Defendants.

FEDERAL DEFENDANTS' RESPONSE TO PLAINTIFF'S MOTION TO AMEND COMPLAINT SOLELY TO INCORPORATE CLAIMS UNDER FEDERAL ADVISORY COMMITTEE ACT ((“FACA”), 5 U.S.C. APP. 2 §§ 1-16) [DOC. NO. 106]

Plaintiff Lystn, LLC (Lystn) seeks to add new claims to its complaint alleging that the Association of American Feed Control Officials (AAFCO) and FDA have somehow violated the Federal Advisory Committee Act (FACA), 5 U.S.C. app. 2 §§ 5, 10, because AAFCO's executive director restricted Lystn's access to certain AAFCO material and meetings during the pendency of this litigation. The Federal Defendants oppose Lystn's motion to amend because, as even Lystn concedes, its proposed FACA claim is wholly unrelated to the existing litigation, for which three fully-briefed motions to dismiss are now pending. Thus, prejudice and judicial economy considerations militate in favor of denying Lystn's motion. Supplementation would also be futile because Lystn has neither plausibly alleged that AAFCO is an advisory committee subject to FACA nor exhausted the administrative remedy for such a claim, making the proposed amended complaint subject to dismissal.[1]

BACKGROUND

I. The Federal Advisory Committee Act And Related Regulations

FACA was enacted to curb the proliferation of expensive and unnecessary commissions, boards, and panels set up to advise the President and federal agencies. 5 U.S.C. app. 2 § 2(b). Through this statute, Congress sought to ensure that advisory committees "be established only when essential and that their number be minimized; that they be terminated when they have outlived their usefulness; that their creation, operation, and duration be subject to uniform standards and procedures; that Congress and the public remain apprised of their existence, activities, and cost; and that their work be exclusively advisory in nature." *Public Citizen v. U.S. Dep't of Justice*, 491 U.S. 440, 446 (1989).

FACA defines an "advisory committee" as "any committee, board, commission, council, conference, panel, task force, or other similar group . . . which is . . . established or utilized by one or more agencies . . . in the interest of obtaining advice or recommendations for . . . one or more agencies or officers of the Federal Government . . . ." 5 U.S.C. app. 2 § 3(2). Groups that meet this definition must comply with certain procedural requirements, including announcing upcoming meetings in the Federal Register and opening them to the public (unless an exception applies), *id.* § 10(a)(1)-(2), and providing public access to the committee's "records, reports, transcripts, minutes, appendixes, working papers, drafts, studies, agenda, or other documents," *id.* § 10(b). FACA also requires that the membership of advisory committees established by legislation be "fairly balanced in terms of the points of view represented and the functions to be performed" and that the "advice and recommendations of the advisory committee will not be inappropriately influenced by the appointing authority or by any special interest." *Id.* § 5(b)(2)-(3). "To the extent they are applicable," the same guidelines "shall be followed by the President, agency heads, or other Federal officials in creating advisory committees." *Id.* § 5(c).

---

[1] In addition to presenting the arguments herein, the Federal Defendants incorporate by reference their clarification regarding Lystn's certificate of compliance with D. C. Colo. L. Civ. R. 7.1(a), Doc. No. 110.

The General Services Administration provides guidelines for FACA, which are codified at 41 C.F.R. Part 102-3. Of relevance here, the regulations specify that "[t]he function of advisory committees is advisory only" unless a statute or Presidential directive provides otherwise, 41 C.F.R. § 102-3.30(e), and advisory committee meetings are "held with the approval of an agency for the purpose of deliberating on the substantive matters upon which the advisory committee provides advice or recommendations," *id.* § 102-3.25. FDA's advisory committee regulations are codified at 21 C.F.R. Part 14. Among other things, these regulations cover the procedures for establishing advisory committees, nominating and selecting members, holding public meetings, and preparing and maintaining records. FDA's standing advisory committees, the dates they were established, and their functions are set forth in these regulations, and, notably, AAFCO is not identified as a standing advisory committee. *See* 21 C.F.R. § 14.100. Regulations also provide an administrative remedy for allegations of noncompliance with FACA or the Part 14 regulations for use before a party resorts to legal action in court. *See* 21 C.F.R. § 14.7.

II. Procedural History And Proposed Amendments To The Complaint

On July 5, 2019, Lystn filed a complaint and a motion for a preliminary injunction seeking judicial review under the Administrative Procedure Act (APA), 5 U.S.C. § 704, of FDA

Compliance Policy Guide (CPG) 690.800, "*Salmonella* in Food for Animals," a nonbinding guidance document concerning the health risks posed by animal food contaminated with *Salmonella*. The CPG provides factors for FDA field staff to consider when deciding whether to recommend to headquarters offices that animal food contaminated with *Salmonella* be refused admission into the United States if the food is offered for import or, if such food is not an import, that a civil in rem seizure be initiated. Although FDA initiates enforcement action under the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. §§ 301 *et seq.*, and not guidance documents, and has taken no enforcement action against Lystn, Lystn nevertheless alleges that FDA is somehow "enforcing" the CPG against Lystn through Defendant AAFCO, a private, nonprofit, voluntary membership organization,[2] and Defendant Colorado Department of Agriculture (Colorado). *See, e.g.,* Doc. No. 1 ¶¶ 86, 98, 101. Lystn seeks an injunction prohibiting FDA from "promulgating th[e]" CPG or taking enforcement action. *Id.* ¶ 131. Fully briefed and pending before the Court are Lystn's motion for a preliminary injunction, three motions to dismiss the existing complaint, and two motions for jurisdictional discovery.[3]

On November 12, 2019, Lystn moved for a temporary restraining order (TRO) on the basis of a November 5, 2019 email from AAFCO's executive director notifying Lystn that its access to certain AAFCO resources and meetings would be restricted pending resolution of this lawsuit. Doc. No. 104. Lystn claimed that AAFCO's decision violates several provisions of FACA. *Id.* at 8. The Court denied Lystn's TRO motion on November 14, 2019, because Lystn sought relief unrelated to that requested in its complaint. Doc. No. 105 at 5. The Court also rejected Lystn's request to "graft" the FACA claim from its TRO motion into its complaint. *Id.*

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[2] AAFCO was established in 1909 with the goal of keeping interstate commerce in animal feed freely flowing by developing uniform model laws for state legislatures to consider. *See* "AAFCO: The People Behind Animal Feed and Pet Food," *available at* https://www.aafco.org/Portals/0/SiteContent/Announcements/2019_AAFCO_The_People_behind_Animal_Feed_and_Pet_Food_082919.pdf?v20190926. AAFCO provides a forum for state and federal regulatory agencies and industry to develop such model bills. *Id.* The Court may consider AAFCO's website because Lystn's complaint, Doc. No. 1, explicitly references it, *id.* ¶ 32 & n.20. *See Jacobsen v. Deseret Book Co.*, 287 F.3d 936, 941 (10th Cir. 2002).

[3] All six of these motions were fully briefed as of October 22, 2019, when the Federal Defendants, AAFCO, and Colorado filed replies in support of their respective motions to dismiss.

The very next day, Lystn filed the instant motion to amend, together with a redlined complaint presenting its new FACA allegations. Doc. No. 106. Lystn generally alleges that AAFCO either conspires with FDA, does FDA's bidding, or regulates instead of FDA. Doc. No. 106, Ex. A ¶¶ 142-44, 152. For example, Lystn claims that AAFCO is "FDA's explicit 'partner'" for the Animal Feed Regulatory Program Standards (AFRPS)—a program that Lystn alleges "forms the enterprise of conspiracy" between FDA and AAFCO, presumably to enforce FDA's CPG,[4] Doc. No. 106, Ex. A ¶ 143—and that FDA "subcontract[ed] out its regulatory authority" to AAFCO, *id.* ¶ 152. Lystn also cites several documents that it misreads in an effort to bolster its assertion that AAFCO is an advisory committee. *See* discussion *infra* pp. 9-12. Noticeably absent from Lystn's proposed complaint are any well-pleaded and plausible allegations that AAFCO acts as an advisory committee by providing advice or recommendations to FDA.

Undeterred, Lystn claims that AAFCO has allegedly violated FACA's requirements for open meetings, fair balance of advisory committee membership, and inappropriate influence on advisory committee advice by restricting Lystn's access to certain AAFCO resources and meetings during the pendency of this litigation. Doc. No. 106, Ex. A ¶¶ 155, 158.d. Lystn seeks a declaration that FDA and AAFCO violated particular FACA provisions, as well as mandamus relief compelling AAFCO to "rescind[] the ban." *Id.* at 39-40.

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[4] Lystn does not identify the object of the purported conspiracy, but rather merely asserts that "the complaint tells this story adequately." Doc. No. 106, Ex. A ¶ 143.

LEGAL STANDARDS

A court may "on just terms, permit a party to serve a supplemental pleading setting out any transaction, occurrence, or event that happened after the date of the pleading to be supplemented." Fed. R. Civ. P. 15(d). Courts apply the same standard when deciding whether to permit a party to supplement a pleading under Rule 15(d) as they do for amendment of a pleading under Rule 15(a)(2). *Sw. Nurseries, LLC v. Florists Mut. Ins., Inc.*, 266 F. Supp. 2d 1253, 1256 (D. Colo. 2003). Leave to amend or supplement may be denied for reasons including "undue prejudice to the opposing party" and "futility of amendment." *Frank v. U.S. West, Inc.*, 3 F.3d 1357, 1365 (10th Cir. 1993). The requirement to freely give leave to amend does not apply when amendment would be futile, which occurs when a complaint, as amended or supplemented, would be subject to dismissal. *See T.V. Commc'ns Network, Inc. v. Turner Network Television, Inc.*, 964 F. 2d 1022, 1028 (10th Cir. 1992).

To survive a motion to dismiss under Rule 12(b)(6), "a complaint must contain sufficient factual matter, accepted as true, to 'state a claim to relief that is plausible on its face.'" *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009) (quoting *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 570 (2007)). A complaint consisting of "[t]hreadbare recitals of the elements of a cause of action, supported by mere conclusory statements," is subject to dismissal. *Id.* "The nature and specificity of the allegations required to state a plausible claim will vary based on context," *Kan. Penn Gaming, LLC v. Collins*, 656 F.3d 1210, 1215 (10th Cir. 2011), and courts should draw on their "judicial experience and common sense" to resolve this inquiry, *Iqbal*, 556 U.S. at 679.

ARGUMENT

I. Lystn's Motion Should Be Denied Because The Proposed Complaint Would Add A New Cause Of Action Unrelated To The Pending Lawsuit

Lystn's proposed FACA claim is a new and distinct cause of action wholly unrelated to the existing APA challenge to FDA's CPG. Indeed, Lystn repeatedly acknowledges how separate and unrelated its FACA claim is to the pending lawsuit: "there are no other changes affecting or altering the claims currently under review," "none of the [proposed amendments] disturb or otherwise involve the existing claims or factual averments underlying them," "Plaintiff has intentionally avoided making *any* changes other than inserting its claims under FACA . . . ." Doc. No. 106 ¶¶ 2, 9, 11 (emphasis in original). The purpose of Rule 15(d) is to "make pleadings a means to achieve an orderly and fair administration of justice," *Griffin v. Cty. Sch. Bd. of Prince Edward Cty.*, 377 U.S. 218, 227 (1964), and the Rule "cannot be used to introduce a 'separate, distinct, and new cause of action,'" *Sessing v. Sherman*, 708 F. App'x 417, 418 (9th Cir. 2017) (quoting *Planned Parenthood of S. Ariz. v. Neely*, 130 F.3d 400, 402 (9th Cir. 1997)).[5] Indeed, "when the matters alleged in a supplemental pleading have no relation to the claim originally set forth and joinder will not promote judicial economy or the speedy disposition of the dispute between the parties, refusal to allow the supplemental pleading is entirely justified." Charles Alan Wright & Arthur R. Miller, Federal Practice and Procedure § 1506 at 271 (3d. ed.

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[5] Motions to supplement complaints are often denied for this reason. *See, e.g., Polansky v. Wrenn*, No. 12-cv-105-PB, 2013 U.S. Dist. LEXIS 38617, at *9-*11 (D.N.H. Feb. 22, 2013) (denying motion to add unrelated claim in part because summary judgment motions on existing complaint were pending); *Graham v. Stansberry*, No. 5:07-CT-3015-FL, 2008 U.S. Dist. LEXIS 64067, at *11-*12 (E.D.N.C. Aug. 20, 2008) (unrelated claims "would unnecessarily complicate the matter and cause defendants undue prejudice"); *Johnson v. City of Converse*, No. SA-01-CA-0724 IV (NN), 2002 U.S. Dist. LEXIS 25924, at *8 (W.D. Tex. Nov. 21, 2002) ("it would be neither necessary nor even particularly efficient" to adjudicate unrelated claim).

2010). Lystn's attempt to add an unrelated claim should be denied because it would not serve the interest of efficiency or judicial economy to adjudicate the FACA claim in this lawsuit, particularly since several motions concerning the existing complaint, including three motions to dismiss, are fully briefed and pending decision.[6]

II. Lystn's Motion Should Be Denied As Futile Because Lystn Does Not Plausibly Allege That AAFCO Is An Advisory Committee Subject To FACA

Even if its proposed new claim were not wholly unrelated to the pending claim in this lawsuit, Lystn fails to state a plausible FACA claim, and supplementation would therefore be futile. Contrary to Lystn's allegations, the requirements of FACA do not apply to every group with whom a federal agency interacts. *See Public Citizen*, 491 U.S. at 464 (rejecting a "literalistic reading" of FACA that "would catch far more groups and consulting arrangements than Congress could conceivably have intended"). Instead, FACA applies only to committees "established or utilized" by agencies "in the interest of obtaining advice or recommendations for . . . agencies or officers of the Federal Government . . . ." 5 U.S.C. app. 2 § 3(2)(C).[7]

"[A]n advisory panel is 'established' by an agency only if it is actually formed by the agency." *Byrd v. U.S. EPA*, 174 F.3d 239, 245 (D.C. Cir. 1999). In this case, Lystn neither alleges that FDA "established" AAFCO nor pleads any facts suggesting that FDA "actually formed" AAFCO. Instead, Lystn asserts that FDA "utilizes" AAFCO. Doc. No. 106, Ex. A ¶

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[6] Lystn tacitly acknowledges that its attempt to inject an entirely new cause of action at this stage raises prejudice and efficiency concerns when it urges that the new FACA claim should not "disturb and/or otherwise derail the Court's consideration of the motions to dismiss" or "otherwise reset these proceedings." Doc. No. 106 ¶¶ 11-12.

[7] FACA also applies to advisory committees "established by statute or reorganization plan" or "established or utilized" by the President, 5 U.S.C. app. 2 § 3(2)(A)-(B), but Lystn does not allege the existence of either of these predicates.

155. The Supreme Court has interpreted the term "'utilized' narrowly to prevent FACA from sweeping more broadly than the Congress intended." *Byrd*, 174 F.3d at 245. Consequently, "utilized" is a term of art related to "established" that "clarif[ies] that FACA applies to advisory committees established by the Federal Government in a generous sense of that term, encompassing groups formed indirectly by quasi-public organizations such as the National Academy of Sciences 'for' public agencies as well as 'by' such agencies themselves." *Public Citizen*, 491 U.S. at 462. As a result, the term "utilized" covers only "quasi-public" groups and groups that are "amenable to the strict management by agency officials." *Id.* at 457-58.

To the extent that Lystn's use of "quasi-governmental" to describe AAFCO may be construed to allege that AAFCO is a "quasi-public" organization and thus subject to FACA, Doc. No. 106, Ex. A ¶ 144, that bare allegation devoid of any supporting facts cannot be taken as true. *See, e.g., Alpenglow Botanicals, LLC v. United States,* 894 F. 3d 1187, 1195 (10th Cir. 2018) (under *Twombly* and *Iqbal*, conclusory statements "are not entitled to the assumption of truth"). Moreover, "quasi-public" means a "semiprivate entity the Federal government helped bring into being," *Public Citizen*, 491 U.S. at 463, whereas AAFCO is a private organization established more than 100 years ago, *see supra* p. 4 & n.2; *see also Food Chem. News v. Young*, 900 F.2d 328, 333 (D.C. Cir. 1990) (panel managed by the Federation of American Societies for Experimental Biology (FASEB) to provide advice to FDA was not subject to FACA partly because "FASEB is a private organization" and thus does not have "quasi-public status").

Lystn's primary allegations regarding AAFCO fare no better. Lystn generally asserts that FDA "utilizes" AAFCO, Doc. No. 106, Ex. A ¶ 155, but that term means more than simply "use." Instead, it refers to the "stringent standard" of showing that an agency exercises "actual management or control of the advisory committee," *Washington Legal Fnd'n v. U.S. Sentencing Comm'n*, 17 F.3d 1446, 1450 (D.C. Cir. 1994), and not, for example, that an agency exerts influence over or participates in a group's activities, *Byrd*, 174 F.3d at 246, or uses a group's work product, *see Sofamor Danek Grp. v. Gaus*, 61 F.3d 929, 936-37 (D.C. Cir. 1995). None of the scant "facts" Lystn presents show that FDA exercises "actual management or control" over AAFCO.

For example, Lystn alleges that a memorandum of understanding (MOU) between AAFCO and FDA converts AAFCO into an advisory committee. *See* Doc. No. 106, Ex. A ¶ 152. The MOU, available at https://www.fda.gov/about-fda/domestic-mous/mou-225-07-7001, concerns only AAFCO's Ingredient Definition Request Process, which AAFCO, not FDA, controls.[8] The MOU plainly states that the process "is operated by AAFCO, *with the FDA providing scientific and technical assistance*," that AAFCO may consult with FDA, that FDA may make requests to AAFCO concerning feed ingredient definitions, and that disagreements between AAFCO and FDA are referred to an AAFCO review board composed equally of AAFCO and FDA representatives. *Id.* (emphasis added). Rather than showing that FDA exercises actual management and control over AAFCO and that AAFCO provides advice and recommendations to FDA, the MOU establishes the exact opposite: that FDA's role is essentially to provide advice to AAFCO in a process "operated" by AAFCO. FACA does not apply if the government is giving advice to a private group, *see, e.g., Consumers Union of U.S., Inc. v. Dep't of Health, Educ., & Welfare*, 409 F. Supp. 473, 477 (D.D.C. 1976), nor does FACA apply if the group is operational instead of advisory, as the MOU reflects that AAFCO is with respect to its feed ingredient definition process, *see, e.g.,* 41 C.F.R. § 102-3.40(k); *Public Citizen v. Comm'n on the Bicentennial of U.S. Constitution*, 622 F. Supp. 753, 757-58 (D.D.C. 1985).[9] Because the MOU does not support Lystn's allegations, they should not be accepted. *GFF Corp. v. Associated Wholesale Grocers, Inc.*, 130 F. 3d 1381, 1385 (10th Cir. 1997) ("factual allegations that contradict . . . a properly considered document are not well-pleaded facts that the court must accept as true").[10]

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[8] The court may consider documents attached to pleadings as exhibits, *Oxendine v. Kaplan*, 241 F.3d 1272, 1275 (10th Cir. 2001), or documents whose authenticity is not disputed that are referenced and "are central to the plaintiff's claim," *Jacobsen*, 287 F.3d at 941. Lystn's proposed complaint cites certain attachments, but the material is in fact attached to Lystn's TRO motion. Doc. Nos. 104 &104-1. The MOU is central to Lystn's claim that AAFCO is an advisory committee. Thus, the sources cited in this response may be considered for purposes of resolving the motion to amend.

As for Lystn's reliance on the AFRPS program, that program is "intended . . . to advance efforts for a nationally integrated animal food safety system" and is supported in part by Congress' call for FDA to enhance partnerships with federal and state agencies to further food safety. *See* Doc. No. 62-1, Ex. G at 3, 5. Lystn seizes on the concept of partnership, repeating that AAFCO was FDA's "partner" in developing AFRPS, Doc No. 106, Ex. A ¶¶ 142-43, 146-47, mistakenly assuming that "partner" equals advisory committee. The common meaning of "partner" includes "a person who takes part in an undertaking with another or others, esp[ecially] in a business or company with shared risks and profits." New Oxford American Dictionary 1278 (Angus Stevenson & Christine A. Lindberg, eds., Oxford Univ. Press 3rd ed. 2010). This definition conveys action and cooperation; alleging a partnership is, therefore, the opposite of what Lystn must allege with specific facts to show that AAFCO is an advisory committee, *i.e.*, that AAFCO is under the actual management and control of FDA and provides advice to FDA. Lystn's allegation that AAFCO received "$139,000.00 in income from administering" AFRPS for FDA, Doc. No. 106, Ex. A ¶ 150, is also insufficient to show that AAFCO is an advisory committee. At most, this allegation would suggest that AAFCO is fulfilling an operational role by administering the program, not providing advice and recommendations as an advisory committee would do. *See, e.g., Judicial Watch, Inc. v. Clinton*, 76 F.3d 1232, 1233 (D.C. Cir. 1996) (trust fund was not an advisory committee partly because it was "not primarily advisory in nature," but instead had an operational purpose of collecting and managing funds).[11]

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[9] Indeed, FDA has long designated AAFCO as one of many private groups and organizations that engage in standard setting activities. *See* 21 C.F.R. § 10.95(d)(8).

[10] Lystn baldly asserts that FDA "very plainly noted it considered its authority [to enter into the MOU] in that AAFCO was an Advisory Agency," Doc No. 106, Ex. A ¶ 152, citing an email response to a query about the MOU, *see* Doc. No. 104-1, Ex. S. Nowhere in that response, however, does FDA say that AAFCO is an "Advisory Agency" or advisory committee or that FDA's authority to enter the MOU is based on the establishment of advisory committees. *Id.* To the contrary, the response explicitly states that "FDA *does not oversee AAFCO activities* under the MOU," *id.* (emphasis added), further refuting Lystn's misguided claim that the email is evidence of an advisory committee relationship.

Indeed, Lystn nowhere alleges that AAFCO advises FDA—the sole function of an advisory committee under FACA. *See* 5 U.S.C. app. 2 § 3(2)(C) (an advisory committee is "established or utilized . . . [for] obtaining advice or recommendations for" federal agencies or officers). Lystn does not identify any meetings held by an alleged AAFCO advisory committee for purposes of providing advice to FDA, any advice or recommendations provided by AAFCO to FDA, or any action taken by FDA on the advice or recommendation of an AAFCO advisory committee. *See* 21 C.F.R. § 14.5 (an advisory committee "is utilized to conduct public hearings on matters of importance that come before FDA" and "to provide advice and recommendations" to FDA).

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[11] Lystn also claims that AAFCO "has acted at the behest of the FDA to enforce" FDA policy, Doc. No. 106, Ex. A ¶ 142, another operational allegation that undercuts its attempt to plead that AAFCO is an advisory committee.

In sum, Lystn has not presented a well-pleaded or plausible claim that AAFCO is an advisory committee within the meaning of FACA. Lystn does not allege that FDA established AAFCO, asserts without any factual support that AAFCO is a "quasi-governmental" body, claims that FDA "utilizes" AAFCO despite the plain meaning to the contrary of the material it cites in an attempt to flesh out the claim, and does not allege that AAFCO provides advice or recommendations to FDA. Lystn has therefore failed to "nudge[] [its] claim[] across the line from conceivable to plausible," *Twombly*, 550 U.S. at 570, and its motion to add a FACA claim to the existing complaint should be denied as futile.[12]

III. Lystn's Motion Should Be Denied As Futile Because Lystn Failed To Exhaust The Administrative Remedy For Its FACA Claim

Lystn's motion should also be denied as futile for a reason entirely distinct from its failure to present a well-pleaded and plausible claim for relief—Lystn has failed to exhaust its administrative remedy. It is well-settled "'that no one is entitled to judicial relief for a supposed or threatened injury until the prescribed administrative remedy has been exhausted.'" *McKart v. United States*, 395 U.S. 185, 194 (1969) (quoting *Myers v. Bethlehem Shipbuilding Corp.*, 303 U.S. 41, 50-51 (1938)). Exhaustion permits an agency to "develop the necessary factual background upon which decisions should be based." *Id.* at 193-94. It also promotes judicial efficiency because a claim may be resolved in an aggrieved party's favor by the agency, the proceedings may convince a party not to pursue the matter further, or, if judicial review is sought, the administrative proceedings will provide a record for the court's consideration. *See Woodford v. Ngo*, 548 U.S. 81, 89 (2006).

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[12] In addition, Lystn's claim for relief due to a purported violation of the requirement in 5 U.S.C. app. 2 § 5(b)(3) to ensure that an advisory committee's recommendations will not be "inappropriately influenced by the appointing authority or by any special interest," Doc. No. 106, Ex. A ¶ 158.d, is not justiciable. *See Colo. Envt'l Coal. v. Wenker*, 353 F.3d 1221, 1230-32 (10th Cir. 2004) (concluding that the statute provides "no meaningful standard of review for a court to apply" to determine what might constitute "inappropriate influence"). Amending the complaint to add a claim that cannot be reviewed would therefore be futile.

Lystn could have, but did not, file a citizen petition pursuant to 21 C.F.R. §§ 10.25 and 10.30. FDA regulations require a party to use this process to "request that the Commissioner take or refrain from taking any form of administrative action . . . before any legal action is filed in a court . . . ." 21 C.F.R. § 10.45(b). FDA's response to a citizen petition would be final agency action subject to judicial review. *Id.* § 10.45(d). Courts have often dismissed cases for failure to follow these regulations. *See, e.g., Cody Labs., Inc. v. Sebelius*, 446 F. App'x 964, 969-70 (10th Cir. 2011) (affirming dismissal of claim against FDA on exhaustion grounds and citing cases similarly resolved).

Directly on point, FDA's advisory committee regulations provide that "[t]he provisions of § 10.45 relating to exhaustion of administrative remedies are applicable" to allegations that the FDA Commissioner or an advisory committee has not complied with FACA or FDA's advisory committee regulations. 21 C.F.R. § 14.7(a). The regulations also provide for expedited review in certain circumstances. *Id.* § 14.7(a)(2). The broadness and uncertainty of Lystn's allegations regarding AAFCO highlight why they should have been presented first to FDA, not in a claim added to pending litigation on a wholly different matter—permitting FDA to consider the allegations first would at least crystallize the issues in contention and develop a record for judicial review. *See Parisi v. Davidson*, 405 U.S. 34, 37 (1972) (exhaustion allows an agency to make a factual record, apply its expertise, and correct its own errors before judicial review).

CONCLUSION

For the foregoing reasons, Lystn's motion to amend should be denied. Should the Court grant Lystn's motion, the Federal Defendants request that the Court not vacate the numerous other motions related to the existing complaint and limit subsequent responses and/or briefing to the FACA allegations.

Dated: December 6, 2019

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CERTIFICATE OF SERVICE

The undersigned hereby certifies that on December 6, 2019, I caused to be served via ECF a true and correct copy of the foregoing document to all counsel of record.

/s/ Meredith B. Healy
MEREDITH B. HEALY
Trial Attorney

**IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLORADO**

Civil Action No. 19-cv-01943-PAB-KLM

LYSTN, LLC d/b/a ANSWERS™ PET FOOD,

Plaintiff,

v.

FOOD AND DRUG ADMINISTRATION, et al.,

Defendants.

RESPONSE OF DEFENDANT ASSOCIATION OF AMERICAN FEED CONTROL OFFICIALS (AAFCO) TO MOTION TO AMEND COMPLAINT (ECF NO. 106)

Introduction

AAFCO opposes Plaintiff's Motion to Amend Complaint Solely to Incorporate Claims under Federal Advisory Committee Act ("Motion," ECF No. 106). First, Plaintiff has provided no basis for the amendment, let alone one that justifies its prejudice. Second, the amendment would be futile because the Federal Advisory Committee Act (FACA) does not create a private right of action, AAFCO is not an advisory committee, and Plaintiff lacks standing.

Conferral Violations

As a preliminary matter, AAFCO notes Plaintiff's serial violations of this Court's conferral requirement. D.C.COLO.LCivR 7.1 Most recently, the Motion's certification of compliance blatantly misrepresented the facts. The Motion falsely stated that Defendants had "remained mute," (Motion ¶ 3), when all three Defendants emailed Plaintiff's counsel the day before the Motion was filed to oppose the amendment. (ECF No. 110-1 at 1-3).[1] Unfortunately, this is not the first time the parties have faced this problem. Before filing the Application for a Temporary Restraining Order and/or Preliminary Injunction (ECF No. 104), Plaintiff refused to engage in meaningful conferral.[2] In place of a conferral certificate, Plaintiff falsely stated AAFCO refused to reverse its actions. (*Compare id.*, *with* ECF No. 104-1 at 4). Plaintiff has also violated the conferral requirement with ECF No. 70 (lacking certificate of conferral because no conferral effort was made) and ECF Nos. 47 and 48 (identifying that, contrary to ECF No. 45's conferral certificate, Plaintiff had actually made no effort to confer).

Argument

I. Justice does not require Plaintiff be allowed to add an unrelated claim without justification, especially when the amendment would cause prejudice.

Because the window for an amendment as a matter of course has closed, the Court should grant the amendment only when "justice so requires." F.R.C.P. 15(a). "The principal factors which are considered in connection with the offer of an amendment are, first, whether it will cause delay and, second, whether the adversary will suffer prejudice." *R. E. B., Inc. v. Ralston Purina Co.*, 525 F.2d 749, 751 (10th Cir. 1975). Plaintiff has not provided a single reason justice favors the amendment. In the explanation of the amendment's "basis," Plaintiff describes the case's posture and the limited nature of the amendment but offers no justification for the relief sought.[3] (Motion at 2-3).

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[1] Plaintiff's counsel sent another email at 6:29 that evening, indicating that, though he still planned to amend, he would state his intent that "the outstanding motions [to dismiss] remain sub-judice and Ripe for Determination." (ECF No. 110-2). AAFCO's counsel replied at 12:39 p.m. the following day reiterating AAFCO's opposition, and Plaintiff filed the Motion several minutes later. Even if Plaintiff had not received AAFCO's second email before choosing to file—which was premature given that just a few business hours had passed since Plaintiff sent his follow-up email—all Defendants' positions were clear from their earlier emails, and Plaintiff's representation that no Defendant had responded was patently false.

[2] Plaintiff's counsel's email objected on unidentified grounds to AAFCO's decision to limit Plaintiff's access to AAFCO's resources and stated he intended to seek unidentified relief. AAFCO's counsel responded that same day, requesting that Plaintiff's counsel identify "the law Plaintiff believed AAFCO would be violating" in order to "allow a meaningful conferral." (ECF No. 110-1 at 4). Rather than responding, Plaintiff filed the Motion.

On the other side of the balancing scale is the significant burden the amendment would cause. Even Plaintiff acknowledges that justice does not support the typical consequence of granting the Motion: upending Defendants' fully briefed motions to dismiss. *Goings v. Sumner Cty. Dist. Attorney's Office*, No. 13-1107-RDR, 2013 WL 5406444, at *2 (D. Kan. Sept. 25, 2013) ("Because the motion to amend is granted, defendants' pending motion to dismiss . . . is MOOT."). Each Defendant filed a dismissal motion, and, though Plaintiff could have sought to amend the Complaint rather than responding, it chose to proceed—thus prompting Defendants to invest resources in replies and the Court to begin its analysis. Mooting the fruit of these investments and beginning the process anew would impose prejudice, which Plaintiff does not even argue is warranted. (Motion ¶ 9, 11). Because Plaintiff identifies no authority for granting its motion without imposing that prejudice, the prejudice is grounds for denying the Motion.[4]

But, irrespective of whether the amendment would moot the dismissal motions, it would cause prejudice. "Addition of a new claim may have the effect of complicating the proceeding." *R. E. B., Inc.*, 525 F.2d at 752. This is especially true where the two claims are unrelated and subject to different procedures. Plaintiff's Administrative Procedure Act (APA) claim, the only claim pled in the original Complaint, should proceed under the Court's AP Rules.

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[3] Because the Motion failed to provide any basis for the amendment, AAFCO anticipates that Plaintiff may be tempted to raise new arguments in the Reply, but no such arguments may be considered. *SCO Grp., Inc. v. Novell, Inc.*, 578 F.3d 1201, 1226 (10th Cir. 2009) ("[A] party waives issues and arguments raised [in the reply] for the first time.").

[4] If the Court grants the Motion, AAFCO asks that the Court award only the limited relief Plaintiff requests: allowing only the FACA claim to proceed if the dismissal motions are granted.

D.C.COLO.LAPR 1.1(c). Meanwhile, the FACA claim is subject to the standard civil rules. Attempting to follow these two disparate and often conflicting procedures in the same case would be complicated and problematic. For instance, adding the FACA claim would slow the APA claim's otherwise streamlined and accelerated track. And, where discovery might be permitted on the FACA claim, F.R.C.P. 26, Plaintiff could improperly leverage that discovery to bolster the APA claim, for which discovery is impermissible. *Olenhouse v. Commodity Credit Corp.*, 42 F.3d 1560, 1579 (10th Cir. 1994).

That risk of over-complication is especially high in this case, which has already run amok. At the outset, Plaintiff filed an unorthodox complaint, from which Defendants had difficulty even gleaning the claims. (ECF No. 65 at 12). Plaintiff did not try to defend any claim other than APA claim (ECF No. 80), which should never have been brought against AAFCO because it is axiomatically not subject to the APA. 5 U.S.C. §§ 701, 702(b) (the APA applies only to federal agencies). Later, however, Plaintiff began categorizing this an antitrust action (ECF No. 80 at 5), though the Complaint does not allege a conspiracy (ECF No. 1).[5] Fueling the chaos, intervenors—with highly questionable standing (ECF Nos. 95, 111)—have come out of the woodwork, filing their own complaints and improper amendments (ECF No. 108). Now, Plaintiff seeks to add a new, contradictory claim. Though Plaintiff previously asserted AAFCO was an agency, it now alleges AAFCO is a federal advisory committee. Those characterizations are mutually exclusive, 5 U.S.C. § App. 2 § 3(2)(i) (federal agencies are not advisory committees), and Plaintiff's pursuit of both establishes it will say anything to impose fees and other burdens on Defendants. In short, Plaintiff is already playing havoc with rational litigation, and adding a disparate claim on a different procedural track can only exacerbate the problem. Because Plaintiff has provided absolutely no reason for the amendment—let alone one outweighing the demonstrable prejudice to Defendants—the amendment should be denied.

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[5] The Motion's own title confirms that the requested amendment does not add a conspiracy claim at this interval either.

II. The Motion should be denied because amendment would be futile.

The Court should deny a motion to amend if amendment would be futile. *Jefferson Cty. Sch. Dist. No. R-1 v. Moody's Investor's Servs., Inc.*, 175 F.3d 848, 859 (10th Cir. 1999). "A proposed amendment is futile if the complaint, as amended, would be subject to dismissal." *Id.*

A. AAFCO is not subject to personal jurisdiction in Colorado.

Like the original Complaint, the proposed First Amended Complaint ("FAC," ECF No. 106 at 8-49) fails to identify a single relevant contact AAFCO made with this jurisdiction. In fact, the FAC adds no new information supporting this Court's personal jurisdiction over AAFCO.[6] Thus, for the same reasons the original claim against AAFCO should be dismissed for lack of personal jurisdiction (ECF Nos. 65, 91), so, too, should the FAC's new claim.

B. FACA does not create a private right of action.

Alexander v. Sandoval, 532 U.S. 275 (2001), gives courts "no choice but to hold that FACA creates no private right of action." *Judicial Watch, Inc. v. Nat'l Energy Policy Dev.*

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[6] The contact Plaintiff asserts "properly brings AAFCO to this Court" is a contact the FDA—not AAFCO—made with the Colorado Department of Agriculture (CDA). (FAC ¶ 145). Additionally, though the FAC alleges AAFCO "partners" with the FDA in drafting model regulations (*id.* ¶ 146), Plaintiff has made no allegation that AAFCO was involved in Colorado's adoption of those regulations. For example, Plaintiff describes "large sums of money" (*id.*) Colorado allegedly receives to enforce regulations but does not allege the money comes from AAFCO, which it does not. Relatedly, deponent Kristi McCallum does not mention AAFCO at all, but, even if the FAC's creative description of that deposition were accurate, it does not amount to an allegation that AAFCO made contact with Colorado. Rather, the FAC alleges only that AAFCO helped create the AFPRS's program terms, which the FDA and CDA—not AAFCO—allegedly applied to sampling, testing, and reporting in Colorado. (*Id.* ¶ 147).

Group, 219 F.Supp.2d 20, 33 (D.D.C. 2002)). *Alexander* thus supersedes all prior jurisprudence in which a private plaintiff successfully brought a FACA claim. The Tenth Circuit has adopted that conclusion. *Colorado Envtl. Coal. v. Wenker*, 353 F.3d 1221, 1234–35 (10th Cir. 2004) (FACA does not contain "a private right of action for those seeking to enforce the procedural requirements attending the creation and operation of federal advisory committees").

Rather than bringing a free-standing FACA claim, a private plaintiff must use the APA or the federal mandamus statute, 28 U.S.C. § 1361, as the vehicle. *Judicial Watch*, 219 F. Supp. 2d at 42. Plaintiff has done neither of those here. Plaintiff acknowledged the FACA claim does not "involve" the prior APA claim. (Motion ¶ 9). And Plaintiff's off-handed request for "relief in the nature of mandamus" (FAC at 40; *see also id.* at 10 (cursory and unsupported citation to mandamus statute)) does not sufficiently invoke the mandamus statute. Rather, to bring a proper mandamus claim, Plaintiff should have pled, among other elements, that the FDA failed to perform some specific "ministerial duty . . . so plainly prescribed as to be free from doubt." *Judicial Watch*, 2019 F. Supp. 2d at 42. The FAC identifies no such duty or failure.

Even if the FACA issues were properly pled as an APA or mandamus action, AAFCO would not be a proper defendant. As AAFCO has detailed before, it is not a federal agency and thus not subject to the APA. (ECF No. 65 at 10-11). Likewise, the mandamus statute applies only to "an officer or employee of the United States or any agency thereof." 28 U.S.C. § 1361; *see also Gonzalez-Vera v. Townley*, 83 F. Supp. 3d 306, 314 (D.D.C. 2015) (the statute "does not apply to private citizens"). Because Plaintiff does not—and cannot truthfully—allege AAFCO is an officer or employee of a federal agency, Plaintiff cannot bring a mandamus action against AAFCO, rendering the amendment futile.

C. The FAC does not state a claim upon which relief can be granted.

A complaint should be dismissed if the well pled facts do not suggest Plaintiff is plausibly entitled to relief. *Gee v. Pachero*, 627 F.3d 1178, 1183 (10th Cir. 2010); F.R.C.P. 12(b)(6). Conclusory allegations are not well pled facts. *Hall v. Bellmon*, 935 F.2d 1106, 1110 (10th Cir. 1991). "[A] plaintiff's obligation to provide the grounds of his entitlement to relief requires more than labels and conclusions, and a formulaic recitation of the elements of a cause of action will not do." *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 565 (2007) (internal quotations and citations omitted). In assessing the sufficiency of a complaint, the Court must confine its analysis to the complaint itself and documents the complaint references if those documents are central to the claim. *Jacobsen v. Deseret Book Co.*, 287 F.3d 936, 941 (10th Cir. 2002).

The language the FAC adds to the original Complaint relates exclusively to Plaintiff's desired FACA claim. (Motion ¶ 11). Accordingly, the entire amendment is futile if the FAC fails to state a FACA claim. FACA defines an "advisory committee" as a group "(A) established by statute or reorganization plan, or B) established or utilized by the President, or C) established or utilized by one or more agencies, in the interest of obtaining advice or recommendations for the President or one or more agencies or officers of the Federal Government." 5 U.S.C. App. 2 § 3. Plaintiff's position is that AAFCO is an advisory committee because it is a group "utilized" by the FDA. (FAC ¶ 155). However, the FAC's allegation that the FDA utilizes AAFCO per 5 U.S.C. App. 2 § 3 is conclusory and fails to allege the underlying facts the law requires.

The United States Supreme Court narrowly interpreted FACA's use of the word "utilized," writing: "Read unqualifiedly, it would extend FACA's requirements to any group . . . from which the President or an Executive agency seeks advice. We are convinced that Congress did not intend that result." *Pub. Citizen v. U.S. Dep't of Justice*, 491 U.S. 440, 452 (1989). After a detailed analysis of the legislative history and the executive order that prompted FACA, the Court tied the definition of "utilized" to whether the alleged advisory group was "established"—in a "broad understanding of that word"—by the Executive Branch. *Id.* at 461-63. Plaintiff did not allege the FDA established AAFCO,[7] and it could never ethically do so because that allegation would be blatantly untrue. As Plaintiff did not and cannot plead the FDA established AAFCO, AAFCO cannot be an advisory committee, and the FACA claim should be dismissed.

i. The definition of "utilized" should not be expanded.

Other Circuit courts, including the D.C. Circuit, have expanded the definition of "utilized" beyond the boundaries *Public Citizen* erected, but the Tenth Circuit is not among them. Specifically, those Circuits created a second category of advisory committees: those so closely controlled by a federal agency that they have "quasi-public" status. *Food Chem. News v. Young*, 900 F.2d 328, 332 (D.C. Cir. 1990).

As a threshold matter, this Court need not be the first in the Tenth Circuit[8] to adopt this loose interpretation of *Public Citizen.* A close reading of the Supreme Court's opinion reveals that the inquiry into an organization's quasi-public status is only relevant to the "broad" meaning of "established"; specifically, if a federal agency establishes a quasi-public organization that in turn establishes a committee, the "offspring" committee may be subject to FACA. 491 U.S. at 462-63 ("The phrase 'or utilized' therefore appears to have been added simply to clarify that FACA applies to advisory committees established by the Federal Government in a generous sense of that term, encompassing groups formed indirectly by quasi-public organizations.").

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[7] To support the APA claim, the original Complaint alleged AAFCO was "created by local, state, federal, and international regulators." (FAC ¶ 28). Not only does the FAC lack facts to make that conclusory allegation plausible, the allegation that AAFCO was jointly created by a slew of unidentified regulators is not an allegation that AAFCO was established by the FDA. *Aluminum Co. of Am. v. Nat'l Marine Fisheries Serv.*, 92 F.3d 902, 905 (9th Cir. 1996) (groups not "formed by, at the prompting of, or solely for the federal government" are not established by the federal government for FACA's purposes); *Byrd.*, 174 F.3d at 245 (*Public Citizen* narrowly interpreted "established" and "indicated that an advisory panel is 'established' by an agency only if it is actually formed by the agency.")

[8] Though district courts in this Circuit have mentioned the extended interpretation of *Public Citizen*, it was not necessary to the holding, as those plaintiffs properly pled the federal agency established the advisory group. *Strata Production Co. v. Jewell*, No. CV 13-205 JCH-GBW, 2014 WL 12789010, at *15 (D.N.M. Aug. 11, 2014); *Wyoming v. U.S. Dep't of Agric.*, 201 F. Supp. 2d 1151, 1157 (D. Wyo. 2002), *vacated sub nom.* 414 F.3d 1207 (10th Cir. 2005).

Even the D.C. Circuit admitted its broader readings of *Public Citizen*, "actually extended slightly" the Supreme Court's strict definition of "utilize," *Animal Legal Def. Fund, Inc. v. Shalala*, 104 F.3d 424, 430 (D.C. Cir. 1997), which, of course, a Circuit court lacks authority to do. The D.C. Circuit clarified that "the definition given by the [Supreme] Court to an advisory committee utilized by the federal government focuses not so much on how it is used but whether or not the character of its **creating institution** can be thought to have a quasi-public status." *Id.* at 428 (emphasis added); *see also id.* at 429 (*Public Citizen*'s conclusion is "that by employing the term 'utilized,' in addition to 'established,' Congress had in mind an extension of the Act's coverage to include the offspring of 'quasi-public' organizations 'permeated by the Federal government.' After all, that is the only sort of advisory committee the Court recognized as reached by the term 'utilized.'"[9] (quoting *Public Citizen*, citations omitted)). A correct application of the Supreme Court's precedent therefore requires that, because the FAC does not allege the FDA directly or indirectly established AAFCO, the FACA claim must be dismissed.

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[9] The FDA has interpreted "utilize" in "guidelines" for its own analyses. 21 C.F.R. § 14.1(b)(6). As part of "Part 14 – Public Hearing before Public Advisory Committee," the guidelines help determine whether an advisory committee should hold a public hearing, not whether a group is a FACA advisory committee for other purposes. Even if these guidelines were intended to guide a full FACA analysis, they could not properly expand FACA's scope beyond the statute as interpreted by the Supreme Court—especially where the FDA's interpretation of "utilized" is the result of legal analysis rather than special agency expertise.

ii. Even under the extended definition of "utilized," the FDA does not utilize AAFCO as an advisory committee.

Even if this Court adopts the D.C. Circuit's admittedly extended test, Plaintiff's FACA claim should still be dismissed because Plaintiff did not successfully plead AAFCO is so completely under FDA's thumb that it is quasi-public. Even courts that have adopted the extended test provide that only organizations so "closely tied to an agency as to be amenable to strict management by agency officials" are utilized by the federal government. *Food Chem. News*, 900 F.2d at 333 (internal quotation marks omitted). "Participation by an agency or even an agency's significant influence over a committee's deliberations does not qualify as management and control such that the committee is utilized by the agency under FACA." *Byrd v. U.S. E.P.A.*, 174 F.3d 239, 246 (D.C. Cir. 1999) (emphasis, citations, and internal quotation marks omitted). Having voting members from the federal government does not render an organization an advisory committee. *Wash. Legal Found. v. U.S. Sentencing Comm'n*, 17 F.3d 1446, 1451 (D.C. Cir. 1994). And, when the alleged advisory group answers to an organization other than a federal agency, the agency lacks sufficient control. *Id.* This application is so limited that only one organization has been found to have quasi-public status: the National Academy of Sciences. *Animal Legal Def. Fund*, 104 F.3d at 431.

In the FAC, Plaintiff makes unfounded allegations that the FDA "controls" AAFCO and that AAFCO is "quasi-governmental" (FAC ¶ 144), which should be disregarded as conclusory. Meanwhile, the FAC's properly pled facts affirmatively show that the FDA does not, in fact, control AAFCO.

To establish the FDA's alleged control over AAFCO, the FAC relies primarily on AAFCO's and the FDA's references to their "partner[ship]" in developing the Animal Feed

Regulatory Program Standards (AFRPS). (FAC ¶¶ 142-43, 146-47). According to Meriam-Webster Dictionary, a "partner" is "one associated with another especially in an action: associate, colleague."[10] The alleged partnership thus amounts only to FDA's and AAFCO's status as colleagues—not as boss and employee, as would be necessary to show control.

As a second attempt to allege control, the FAC identifies that AAFCO gets a fraction of its funding from FDA grants.[11] (FAC ¶ 150). According to the FAC, the grants show AAFCO's role in developing "model laws" and proposing a definition of "adulterated" pet foods (*id.* ¶¶ 148-49) is "prevalent" (*id.* ¶ 150). But not even Plaintiff argues that the grants plausibly show the FDA wholly controls AAFCO. Indeed, prior cases and common sense reveal that a federal agency does not have strict control over every organization to which it grants partial funding. *People for Ethical Treatment of Animals, Inc. v. Barshefsky*, 925 F. Supp. 844, 847-48 (D.D.C. 1996) (plaintiff did not establish likelihood of successfully showing a group that gets "some of the funding" from the federal government is an advisory committee).

As the only other basis for the FDA's alleged control over AAFCO, the FAC invokes the Memorandum of Understanding between the FDA and AAFCO (MOU, Exhibit 1).[12] That reference renders the MOU central to the claim and allows the Court to look to its contents. The express purpose of the current MOU is to "facilitate the FDA's collaboration with AAFCO in the

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[10] *Partner*, MERRIAM-WEBSTER DICTIONARY, www.merriam-webster.com/dictionary/partner?utm_campaign=sd&utm_medium=serp&utm_source=jsonld.

[11] The FAC incorrectly categorizes as an FDA grant the $139,643 AAFCO in fact received from the Association of Public Health Laboratories to study food sampling methodologies, which is unrelated to the AFRPS program. In recent years, the FDA did provide small grants to AAFCO to host meetings or trainings. All FDA grants AAFCO received in the last five years total only $200,000, and AAFCO secured each one by responding to a public request for proposals.

[12] The current MOU attached at Exhibit 1 is also available at www.fda.gov/about-fda/domestic-mous/mou-225-07-7001.

AAFCO Ingredient Definition Request Process." (Exhibit 1 at 1; *see also id.* ¶ C ("AAFCO will seek advice and a letter of concurrence regarding the suitability of the feed ingredient for its proposed use from the FDA."); *id.* ¶ E (AAFCO may request further consultation from the FDA). The entities' "collaboration" and AAFCO's opportunities to request the FDA's "advice" and "consultation" do not make plausible that the FDA controls AAFCO. To the contrary, they confirm that that the FDA has the power merely to make suggestions, not issue orders.[13]

In absence of the necessary facts showing the FDA strictly controls AAFCO, the FAC relies on an email from the Center for Veterinary Medicine, in which, according to Plaintiff, the FDA admits AAFCO is an advisory committee. (FAC ¶ 152). In this, the FAC badly misrepresents the text of the email, which, in fact, simply identifies the source of the FDA's authority to enter into MOUs. (ECF No. 104-1 at 35). At most, the email implies that, because the FDA and AAFCO entered into an MOU, AAFCO is one of the experts, consumers, users, manufacturers, etc. with which the FDA "consult[s]." But that consultation does not amount to an admission that AAFCO is an advisory committee.

In the end, the FAC contains no well pled facts showing the FDA established or wholly controls AAFCO. Without such facts, the FAC's hollow conclusions cannot carry Plaintiff through *Twombly*'s checkpoint, and the FACA claim should be dismissed.

C. Plaintiff lacks standing to pursue the FACA claim.

The Motion indicates AAFCO has declined to allow "everyone associated with the natural pet food industry and/or sympathetic to Plaintiffs' plight" to attend AAFCO's meetings or access its proprietary materials online. (FAC ¶¶ 153, 155, 156 n. 35). Not only is that incorrect,[14] it is irrelevant because Plaintiff lacks standing to litigate the harms to third parties. Rather, Plaintiff has standing only to assert its own rights and vindicate its own harms. *Aid for Women v. Foulston*, 441 F.3d 1101, 1111 (10th Cir. 2006). The only alleged harm to Plaintiff specifically is that it cannot access AAFCO's online materials and meetings—particularly AAFCO's midyear meeting in January 2020.[15] Because even a favorable decision will not redress that injury, Plaintiff lacks standing to pursue the FACA claim. *Petrella v. Brownback*, 697 F.3d 1285, 1294 (10th Cir. 2012) ("Article III standing will be denied unless it is likely, as opposed to merely speculative, that the injury will be redressed by a favorable decision.").

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[13] Plaintiff's reliance on the MOU is even more problematic for Plaintiff's FACA claim because the FAC categorizes the MOU as a contract. (FAC ¶ 152 (by the MOU, "the FDA was subcontracting out is regulatory authority" to AAFCO)). FACA does not apply to organizations that "have contractual relationships with Federal agencies." *Food Chem. News*, 900 F.2d at 331.

Even if something about AAFCO's partnership with the FDA or the MOU rendered AAFCO an advisory committee, which they do not, AAFCO would still not be an advisory committee for the relevant purposes. Whether a group is an advisory committee is not a binary consideration. Rather, a group can be an advisory committee in some capacities but not others. *Center for Auto Safety v. Cox*, 580 F.2d 689, 694 (D.C. Cir. 1978) ("[D]epending on their specific activities, advisory groups can have shifting identities for purposes of the Advisory Committee Act; i.e., they can serve as advisory committees within the meaning of the Act while performing certain functions and, on other occasions, fall outside the ambit of the Act."). In fact, *Auto Safety* held that even an order subjecting to FACA any future meeting between the agency and organization was too broad. Instead, the court applied FACA only to consultations where the agency looked to the organization for recommendations and, even then, applied only specified FACA provisions to those contacts. *Id.* at 694-95.

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[14] AAFCO actually sent the letter in question to Plaintiff and several of its direct associates because AAFCO reasonably wants to maintain distance from those who are suing it, making blatant misrepresentations about it on the record, and taking other actions in this lawsuit that AAFCO believes are inappropriate and unwarranted. AAFCO has issued refunds for any active subscriptions it terminated. Contrary to the FAC's representations (FAC ¶ 155), AAFCO did not send the letter to all other raw pet food industry representatives. That industry and its viewpoints can thus still be represented at AAFCO's upcoming meetings.

[15] The FAC also seeks enforcement of Section 5 of FACA. Much of Section 5 is not judiciable. *Colorado Envtl. Coal*, 353 F.3d at 1231. Furthermore, Section 5 does not give rise to a claim against AAFCO. It actually requires that Congress enact legislation requiring advisory committees to be "fairly balanced" and "assure that the advice and recommendations of the advisory committee will not be inappropriately influenced" and that federal agencies follow that direction in "creating an advisory committee"—not that advisory committees self-regulate to achieve those goals. 5 U.S.C. App. 2 § 5. Thus, even if Plaintiff had alleged it was injured by the Section 5 violation, any Section 5 claim against AAFCO should be dismissed.

Accordingly, unless AAFCO was at a given time advising the FDA, AAFCO would not need to comply with FACA. FACA would not require that AAFCO open every meeting and online resource, as Plaintiff demands; it would apply only when AAFCO is serving in its advisory capacity. Plaintiff does not allege the documents to which it no longer has access are advisory documents, nor does it allege AAFCO will be advising FDA at upcoming meetings. Thus, even an order requiring AAFCO to comply with FACA when acting in its advisory capacity would not mandate that AAFCO open its upcoming meetings or online resources to Plaintiff. Where lack of access to those meetings and resources is Plaintiff's only alleged harm, the harm could not be redressed by a favorable decision holding that AAFCO is subject to FACA for unrelated purposes.

Conclusion

The Motion is fatally flawed in numerous ways, each of which provides independent grounds for denial. First, the prejudice of allowing the amendment is too great, especially since Plaintiff has offered no justification for the Motion at all. Second, the amendment would be futile. AAFCO is a private organization, which is reasonably and legally declining to throw open its doors for people suing it. For its argument to the contrary, Plaintiff stands exclusively on

FACA, but U.S. Supreme Court precedent makes that position untenable. No private plaintiff may pursue a FACA claim, and, even if it could, it would have to show that the federal government established the alleged advisory committee directly or indirectly, which is undisputedly not the case here. In truth, AAFCO is a private group that sometimes collaborates with the FDA, but that does not subject it to FACA's onerous requirements. Because the FAC fails to plead that AAFCO falls within FACA's extremely narrow application, the amendment should be denied as futile.

Respectfully submitted this 6th day of December, 2019.

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CERTIFICATE OF SERVICE

The undersigned counsel certifies that on the 6th day of December, 2019, a copy of the foregoing was filed with the CM/ECF system, which caused it to be served on:

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From: Weber, Jessica [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=C94A9F2A4C7C491D8CAEBD005CF5FFEA-JESSICA.WEB]
Sent: 12/16/2019 8:27:59 AM
To: Nelson, Eric [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f90377266c0c4a68bf8ac2b4783f8ac9-ENelson]
CC: Lambkin, Sonya [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7d0c915e0dbb4948914f8552e911f30f-Sonya.Lambk]
Subject: RE: Inquiry into (b) (5))

That would be helpful. I know that what is in the assignment and what actually gets inspected are sometimes two different things. Thanks!

Jessica D. Weber

From: Nelson, Eric <Eric.Nelson@fda.hhs.gov>
Sent: Monday, December 16, 2019 8:26 AM
To: Weber, Jessica <Jessica.Weber@fda.hhs.gov>
Cc: Lambkin, Sonya <Sonya.Lambkin@fda.hhs.gov>
Subject: RE: Inquiry into (b) (5))

Jessica, I am unaware of any current action or pending actions by FDA to (b) (5). Doesn't mean there isn't something pending. We can check and see if there were any others assigned for the FY

Eric M Nelson
Director of Compliance
FDA/Center for Veterinary Medicine (HFV-230)
7519 Standish Place
Rockville, MD 20855-2773
office: (240) 402-5642
fax: (240) 276-9241
e-mail: Eric.Nelson@fda.hhs.gov

From: Weber, Jessica <Jessica.Weber@fda.hhs.gov>
Sent: Monday, December 16, 2019 8:19 AM
To: Nelson, Eric <Eric.Nelson@fda.hhs.gov>
Subject: FW: Inquiry into (b) (5))

Circling back on this again. Erin Bubb at PDA was asking if there are any (b) (5) locations under compliance action because they are (b) (5) (b) (5) appears to be ok and that's the (b) (5) (b) (5)

Jessica D. Weber

From: Weber, Jessica
Sent: Wednesday, November 27, 2019 9:42 AM
To: Nelson, Eric <Eric.Nelson@fda.hhs.gov>
Subject: FW: Inquiry into (b) (5))

Hi Eric:

Checking in on this. Our State Liaison was asking about it again. I think the open question was if there were any other locations of (b) (5) that had compliance issues.

Thanks again and have a happy turkey day! I'm making brisket. ☺

Jessica D. Weber

From: Weber, Jessica
Sent: Monday, November 25, 2019 1:36 PM
To: CVM Animal Food Programs <CVMAnimalFoodPrograms@fda.hhs.gov>
Cc: DeClement, JoAnn <JoAnn.DeClement@fda.hhs.gov>; Pack, Randy <Randy.Pack@fda.hhs.gov>
Subject: FW: Inquiry into (b) (5))

Good afternoon CVM!

See below, please. (b) (5) JoAnn DeClement) received a request from Erin Bubb at PA Dept of Ag to check if (b) (5) (b) (5) is under compliance action. Apparently (b) (5) (b) (5) and Erin wanted to make sure there weren't any conflicts.

HAF2E has one of their facilities (b) (5) They recently received an FDA 483, but adequately responded. I was wondering if any of you have any pending compliance actions for other facilities that you are aware of.

Thanks in advance!

Jessica D. Weber

From: DeClement, JoAnn <JoAnn.DeClement@fda.hhs.gov>
Sent: Monday, November 25, 2019 1:29 PM
To: Weber, Jessica <Jessica.Weber@fda.hhs.gov>
Subject: RE: Inquiry into (b) (5))

If you could check with CVM that would be great. I won't offer up any additional info regarding other locations unless she specifically requests it.

Jo-Ann C. DeClement
State Liaison / Investigator

New Jersey District
Voorhees Resident Post
U.S. Food and Drug Administration
T: 856-290-4007
B: 973-452-8481
JoAnn.DeClement@fda.hhs.gov

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From: Weber, Jessica <Jessica.Weber@fda.hhs.gov>
Sent: Monday, November 25, 2019 1:23 PM
To: DeClement, JoAnn <JoAnn.DeClement@fda.hhs.gov>; Pack, Randy <Randy.Pack@fda.hhs.gov>
Subject: RE: Inquiry into (b) (5))

They are not under compliance action. They had a 483 at a recent inspection, responded to it, and I responded back.

They have firms all over the place and I only know about the (b) (5)'. Would you like me to check with CVM and make sure they don't have any pending compliance somewhere else?

Jessica D. Weber

From: DeClement, JoAnn <JoAnn.DeClement@fda.hhs.gov>
Sent: Monday, November 25, 2019 1:17 PM
To: Pack, Randy <Randy.Pack@fda.hhs.gov>; Weber, Jessica <Jessica.Weber@fda.hhs.gov>
Subject: Inquiry into (b) (5))

Hi Randy/Jessica,
I just received a voicemail from Erin Bubb from Pennsylvania Dept. of Agriculture. She called to inquire as to whether or not there are any open compliance actions or on-going investigations involving (b) (5) She explained that she is inquiring because the (b) (5) (b) (5) and she's concerned that there may be a conflict if there is an on-going FDA investigation or compliance action involving the firm. Can you provide an info?

PS - I should note that Ms. Bubb is a FDA Commissioned state official.

Thanks,

Jo-Ann C. DeClement
State Liaison / Investigator

New Jersey District
Voorhees Resident Post
U.S. Food and Drug Administration
T: 856-290-4007
B: 973-452-8481
JoAnn.DeClement@fda.hhs.gov

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From: Klommhaus, Kevin [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=CD18A1B1527044B0BB0248E889E73E11-KEVIN.KLOMM]
Sent: 12/5/2019 9:05:17 AM
To: Lambkin, Sonya [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7d0c915e0dbb4948914f8552e911f30f-Sonya.Lambk]; Nelson, Eric [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f90377266c0c4a68bf8ac2b4783f8ac9-ENelson]; McCoig, Amber [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=daa97064a98f4c249e0a1264311d1169-Amber.McCoi]
Subject: FW: (b) (5) White Paper...Next Steps...
Attachments: (b) (5) White Paper6 (006) with BC comments.docx

FYI

Sincerely

Kevin E. Klommhaus

From: Murphy, Jeanette <Jenny.Murphy@fda.hhs.gov>
Sent: Wednesday, December 4, 2019 3:48 PM
To: Solomon, Steven M <Steven.Solomon@fda.hhs.gov>; Forfa, Tracey <Tracey.Forfa@fda.hhs.gov>; Schell, Timothy <Timothy.Schell@fda.hhs.gov>
Cc: Moxley, Shera <Shera.Moxley@fda.hhs.gov>; Klommhaus, Kevin <Kevin.Klommhaus@fda.hhs.gov>; Groesbeck, Crystal <Crystal.Groesbeck@fda.hhs.gov>; Sennett, Antonia Monique <AntoniaMonique.sennett@fda.hhs.gov>
Subject: FW: (b) (5) White Paper...Next Steps...

Dr. Solomon, Tracey, and Tim,

Over the past year, Kevin Klommhaus and I participated in a workgroup started by Office of Partnerships to look at (b) (5). The resultant white paper is attached and ORA management has asked that this effort move forward.

We wanted to make you aware of the paper in case you were asked. You can review but I don't think that is necessary at this stage. Here are some thoughts from Kevin on this and I agree with his assessment:

(b) (5)

Kevin will be our lead on this project next year and I will be supporting him as needed. We both have (b) (5)

At this point, this email is for your awareness as it does cross (b) (5) efforts. Please don't hesitate to reach out if you have any questions/concerns.

Sincerely,

Kevin and Jenny

From: Weigner, Timothy <Timothy.Weigner@fda.hhs.gov>
Sent: Monday, December 02, 2019 2:40 PM
To: Murphy, Jeanette <Jenny.Murphy@fda.hhs.gov>; Lewis, Glenda R <Glenda.Lewis@fda.hhs.gov>
Cc: Farmer, Laurie <Laurie.Farmer@fda.hhs.gov>; Neves, Priscilla <Priscilla.Neves@fda.hhs.gov>
Subject: (b) (5) White Paper...Next Steps...

Jenny and Glenda,

Reps from CVM and CFSAN (Retail) participated on the workgroup charged with developing a white paper on (b) (5) and I'm thankful for your groups' input and participation. The ORA ACRA, Acting ACRA and Erik Mettler (OPOP, all agree with (b) (5). Several key recommendations came from the workgroup and our office now has the charge to move forward with the next steps, to include brining in outside association representatives (e.g., AFCO, AFDO, NEHA, NACCHO, NALBO, APHL, CFP and NERO (egg safety standards currently under development).

With the Centers' reps participating on the workgroup, do you believe it is important to solicit feedback and awareness from key Center reps (CFSAN – Doug Stearn, CVM – Dr. Solomon and Tracey Forfa) at this time? If yes, do you want to take the lead or would you recommend OP set up a call with your participation?

Timothy Weigner
Director, Division of Standards Implementation

Office of Regulatory Affairs
Office of Partnerships
U.S. Food and Drug Administration
Tele: 301-796-5873
Cell/BB: 240-401-1429
Timothy.weigner@fda.hhs.gov

OP Vision: A global partnership that protects public health.

OP Mission: We make partnerships happen through fostering funding opportunities and promoting mutual reliance.

http://www.fda.gov/regulatorypartners

FDA U.S. FOOD & DRUG ADMINISTRATION
OFFICE OF REGULATORY AFFAIRS

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From: Jason Schmidt [jasonschmidt@ldaf.state.la.us]
Sent: 12/3/2019 10:52:47 AM
To: Burkholder, William [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8d5fda60a4814bd290d84bd28a2a9292-BBURKHOL]; Close, Kathleen [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd8648e9be864bef9bcc85c68bdbe727-Kathleen.Cl]; Conway, Charlotte [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=93384ceea9df43b5b8dbc7d1fb58fe67-CConway]; StateRFR-Cook, Stan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f6957d49d3294f0db5bbb64f49d4f2c6-StanCook]; Earhart, Laura (VDACS) [laura.earhart@vdacs.virginia.gov]; James A. Embry [jae@otsc.tamu.edu]; StateRFR-Ferguson, George [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4dd46592837047d8bb41b6ff84b7f9b7-George.Ferg]; Franklin, Riley [Riley.Franklin@mda.mo.gov]; Gornnert, Jennifer [Jennifer.Gornnert@agr.nh.gov]; Kristen Green [kristen.mary.green@uky.edu]; Kristen Hamilton [kristen.hamilton@isda.idaho.gov]; Tiffany Leschishin [tiffany.leschishin@state.mn.us]; Karissa.McCaw@FreshFromFlorida.com [Karissa.McCaw@freshfromflorida.com]; Nelson, Eric [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f90377266c0c4a68bf8ac2b4783f8ac9-ENelson]; Otero, JoLynn [jotero@nmda.nmsu.edu]; Price, Caitlin T [Caitlin.price@ncagr.gov]; klsimpso@Purdue.edu [klsimpso@purdue.edu]; StateRFR-Therrell, Austin [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2a33cb63b8ec49ad984af69c85ffc3c3-Austin.Ther]
CC: Lizette (AGR) Beckman [lbeckman@agr.wa.gov]
Subject: Re: PFC needs your votes

Thank you everyone!
We have a consensus and the membership has voted in favor of all 4 items. I will send them to MBR for their consideration.

Best,
Jason

Jason Schmidt, MS
Coordinator
Ag Chemistry Programs
Louisiana Department of Agriculture & Forestry
102 Ag Chemistry Building
Baton Rouge, LA 70803
Phone #: (225) 342-5812

On Mon, Dec 2, 2019 at 9:31 AM Jason Schmidt <jasonschmidt@ldaf.state.la.us> wrote:

> Hi all,
> I am poking the bear one final time. The items listed below still need votes to reach a consensus. Wednesday 12/4/2019 is the deadline to vote.
>
> **PF3**
> 4 votes currently
> **PF5**
> 5 votes currently
> **PF7 and preamble**

> 6 votes currently
> **SUIP 27**
>
> 4 votes currently
>
> If you do not have access to the FeedBin, I will happily email you copies of the documents and accept your votes via email. If you do have access to the FeedBin, I would prefer that you vote on the teamboard but will accept your vote via email.
>
> Best,
> Jason
>
> Jason Schmidt, MS
> Coordinator
> Ag Chemistry Programs
> Louisiana Department of Agriculture & Forestry
> 102 Ag Chemistry Building
> Baton Rouge, LA 70803
> Phone #: (225) 342-5812
>
> On Wed, Nov 6, 2019 at 9:16 AM Jason Schmidt <jasonschmidt@ldaf.state.la.us> wrote:
>
> > Hi all,
> > There are a handful of items on the PFC Voting Members teamboard in the AAFCO FeedBin that I have neglected to remind the group about their status. Consider this a 'poke the bear' email. Here is a quick link to that teamboard: https://aafco.mocaworks.com/v25/team/#324784/tb
> >
> > **PF3**
> > A motion and a second has been submitted for this item by James and Charlotte to submit this language to the MBRC for consideration. No votes yet.
> > **PF5**
> > A motion and a second has been submitted for this item by James and Jennifer to submit this language to the MBRC for consideration. Charlotte has vote in favor.
> > **PF7 and preamble**
> > A motion and a second has been submitted for this item by Charlotte and James to submit this language to the MBRC for consideration . Stan has voted in favor.
> > **SUIP 27**
> >
> > A motion has been submitted for this item by Charlotte to submit this language to the MBRC for consideration .
> >
> > If you do not have access to the FeedBin, I will happily email you copies of the documents and accept your votes via email. If you do have access to the FeedBin, I would prefer that you vote on the teamboard but will accept your vote via email if I must.
> >
> > Best,
> > Jason
> >
> > Jason Schmidt, MS
> > Coordinator

Ag Chemistry Programs
Louisiana Department of Agriculture & Forestry
102 Ag Chemistry Building
Baton Rouge, LA 70803
Phone #: (225) 342-5812

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